



**DEPARTMENT OF JUSTICE
Drug Enforcement Administration**

**[Docket No. 17-45]
Ester Mark, M.D.; Decision and Order**

On July 7, 2017, a former Assistant Administrator of the Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Ester Mark, M.D., (hereinafter, Respondent) of Newport Beach, California. Administrative Law Judge Exhibit 1, (OSC) at 1. The OSC proposed to revoke her DEA Certificate of Registration (hereinafter, COR) No. BM5370123, and deny her pending application COR No. W15069021C pursuant to 21 U.S.C. 823(f) and 824(a)(4) for the reason that Respondent's "continued registration is inconsistent with the public interest." *Id.*

In response to the OSC, Respondent timely requested a hearing before an Administrative Law Judge. ALJ-2. The hearing in this matter was held in Santa Ana, California, on January 23-24, 2018. On April 5, 2018, Administrative Law Judge Charles Wm. Dorman (hereinafter, ALJ) issued Recommended Rulings, Findings of Fact, Conclusions of Law and Decision (hereinafter, Recommended Decision or RD), and on May 9, 2018, the Respondent filed exceptions (hereinafter, Resp Exceptions) to the Recommended Decision. The Government did not file any exceptions to the Recommended Decision or a response to Respondent's exceptions. Having reviewed the entire record, I find the Respondent's Exceptions without merit and I adopt the ALJ's rulings, findings of fact, as modified, conclusions of law and recommended sanction with minor modifications, where noted herein.*^A

ORDER

*^A I have made minor modifications to the RD. I have substituted initials or titles for the names of witnesses and patients to protect their privacy and I have made minor, nonsubstantive, grammatical changes. Where I have made substantive changes, omitted language for brevity or relevance, or where I have added to or modified the ALJ's opinion, I have noted the edits with an asterisk, and I have included specific descriptions of the modifications in brackets following the asterisk or in footnotes marked with an asterisk and a letter.

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. BM5370123 issued to Ester Mark, M.D. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny the pending application, control number W15069021C, for renewal or modification of this registration, as well as any other pending application by Ester Mark, M.D., for registration in Florida or California. This Order is effective [insert Date Thirty Days From the Date of Publication in the Federal Register].

D. Christopher Evans,
Acting Administrator.

The Respondent's Exceptions

Respondent filed Exceptions to the RD on May 9, 2018. Exceptions "shall include a statement of supporting reasons for such exceptions, together with evidence of record (including specific and complete citations of the pages of the transcript and exhibits) and citations of the authorities relied upon." 21 CFR 1316.66. For the most part, the Respondent's Exceptions not only fail to comply with this regulatory requirement, but also lack evidentiary support in the Administrative Record. I am addressing some of these Exceptions in the beginning and have included some throughout the record where relevant. Others are repetitive of Respondent's Post-Hearing Brief and were addressed by the ALJ in the adopted Recommended Decision herein.

Respondent's Exceptions to the Findings of Fact

The Respondent lists sixty-eight "Proposed Findings of Fact," which fall in two categories: proposed findings that mirror those made by the ALJ, and those that supplement the findings of fact made by the ALJ. As to the former, the Respondent, in essence, adopts the ALJ's findings of fact. Consequently, I decline to consider those proposed findings, if intended

as exceptions. As to the latter, I reject the Respondent's proposed factual findings that differ from those made by the ALJ.^{*B} Those findings conflict with the Respondent's pre-hearing stipulations, lack evidentiary support in the Administrative Record, have no relevance to the allegations sustained by the ALJ, or constitute arguments rather than factual allegations.

Lastly, the Respondent's proposed findings of fact omit many factual findings made by the ALJ. To the extent Respondent intended such omissions as exceptions to those factual findings, I reject those exceptions, having concluded that the Administrative Record supports the ALJ's factual findings, as modified by this Decision and Order.

Storage Violations

The ALJ sustained the allegation that Respondent violated 21 CFR 1301.75(b). RD, at 33. Although the controlled substances observed in Respondent's office on two occasions were not stored in a securely locked, substantially constructed cabinet, as required by 21 CFR 1301.75(b), Respondent argues that her extra security measures demonstrate substantial compliance with this regulation. Resp Exceptions, at 13-17. She further argues that DEA has

^{*B} Specifically, I reject the following proposed findings of fact as there is no evidence in the record to support them or because they were irrelevant: law enforcement personnel executed a search warrant at her residence on June 12, 2014 (Resp Exceptions, Proposed Finding of Fact I.6, at 5); testosterone is a Schedule IV controlled substance (*id.* at I.13.5); Respondent's office "was a separate, closed of [sic] area from where patients were seen" (*id.* at 5)(the record does not support this finding—her sworn statement says she sees them "in my—you know, downstairs" GE-12, at 34); the Respondent's husband agreed to purchase a safe (Resp Exceptions, Proposed Finding of Fact II.8, at 6); with the exception of the first sentence, the Respondent's discussion of patient charts (Resp Exceptions, Proposed Finding of Fact II.13, at 6-7); the Respondent provided investigators a dispensing log (Resp Exceptions, Proposed Finding of Fact II.14, at 7); the Government did not introduce in evidence a property receipt for invoices (Resp Exceptions, Proposed Finding of Fact II.18, at 7); investigators neglected to determine the expiration dates of the controlled substances they inventoried (Resp Exceptions, Proposed Finding of Fact II.19, at 7); reference to the Respondent's Medical Board interview (Resp Exceptions, Proposed Finding of Fact II.22, at 8); the Respondent called the pharmacy to order medications (Resp Exceptions, Proposed Finding of Fact III.3, at 8); the investigator never mentioned prescriptions (Resp Exceptions, Proposed Finding of Fact III.6, at 9); the Government did not introduce in evidence the search warrant (Resp Exceptions, Proposed Finding of Fact IV.1, at 9); the Government took an additional inventory for which it did not include a property receipt—the receipt is found in GE-14 for the inventory referenced in the cited transcript pages (Resp Exceptions, Proposed Finding of Fact IV.6, at 10); records of medications ordered by the Respondent (Resp Exceptions, Proposed Finding of Fact V.2, at 11); the respondent's discussion about the standard of care in California (Resp Exceptions, Proposed Finding of Fact V.4 – V.9, at 11); the prescriptions in Exhibit 7 did not include any prescriptions written by the Respondent (Resp Exceptions, Proposed Finding of Fact V.10, at 11); the Respondent's discussion about dosing instructions (Resp Exceptions, Proposed Finding of Fact V.11, at 11); seven prescriptions were not obtained outside the California standard of care (Resp Exceptions, Proposed Finding of Fact V.12, at 12); the Respondent's discussion about E-Compounding and corresponding responsibility (Resp Exceptions, Proposed Finding of Fact V.13, at 12); and the Respondent's discussion about Dr. Munzing's expert testimony (Resp Exceptions, Proposed Finding of Fact V.14, at 12).

not established *prima facie* case on this allegation due to the absence of evidence regarding whether her office door had a lock. *Id.* Respondent refers to her sworn interview, where she described a variety of security measures on her home and office, but the ALJ concluded that the probative value of such testimony is substantially diminished because the DEA was not a party to the proceeding. RD, at 31, n.14. The ALJ also determined that any evidence of an office door lock would be inconsequential, where the room was not set aside solely for the storage of controlled substances. *Id.* at 31. I agree with the ALJ’s decision as outlined below, and I note that in particular, even if the Respondent could claim confusion as to whether her storage of controlled substances provided adequate security to be in compliance with the regulatory requirements, the record supports a finding that she was told by DEA and state investigators very clearly on several occasions that it was not. *See e.g.*, GE-12, at 79 (transcript of sworn interview on April 4, 2014, “just so you know, the Federal regulations require that they be stored in a metal locked cabinet”); *see also* Tr. 23, 36, 130 (DEA and state investigators testifying that Respondent was told on March 14, 2014, to purchase a safe to store the controlled substances). Despite being told repeatedly that her security was not adequate, at the time that the search warrant was executed on June 13, 2014, Respondent had done nothing to further secure the controlled substances.*^C

Recordkeeping and Prescribing

Respondent contends that state and federal investigators “never told [her] or advised [her] to make sure [she] had an inventory readily available.” *Id.* at 18. The regulations clearly require that Respondent maintain an inventory, and furthermore, that “every inventory and other records required to be kept under this part must be kept by the registrant and be available, for at least 2 years from the date of such inventory or records, for inspection and copying by authorized

^{*C} Additionally, the un rebutted evidence regarding Respondent’s other violations of law are enough to support the finding that Respondent’s continued registration is inconsistent with the public interest.

employees of the Administration.” 21 CFR 1304.04. Respondent never produced an inventory as the regulations required. Respondent contends in her Exceptions that DEA and state investigators should have “help[ed] her fix [her] mistakes or give[n her] a deadline to update [her] recordkeeping.” Resp Exceptions, at 18. DEA’s statutory mandate is to ensure compliance with the CSA and its implementing regulations. Respondent showed little aptitude for coming into compliance given that she did not secure her controlled substances after repeated notifications that the storage was not adequate.

Respondent also contends that she keeps dispensing records both in the log that she introduced and also in her patient files; however, she introduced no patient files to explain the discrepancies in her stock of controlled substances. *Id.* at 19. I find that the ALJ addressed all of the arguments in Respondent’s Exceptions related to the dispensing logs herein.

Regarding her prescribing practices, Respondent contends that the AMA Code of Ethics “does not forbid practitioners from treating themselves nor prescribing controlled substances. In general, physicians should not treat themselves or members of their own families, but it is acceptable in some circumstances.” *Id.* at 23. She then lists circumstances where it might be appropriate to so prescribe, none of which have any relevance here, because she has presented no evidence on the record as to her rationale for issuing the prescriptions to her husband, and she failed to maintain proper documentation supporting those prescriptions by which their legitimacy could be assessed. *See* FF 45. Additionally, even if there were a legitimate reason for her to have prescribed to her husband, there is more than enough evidence that Respondent issued these prescriptions outside the usual course of the professional practice and beneath the standard of care due to the fact that she violated state law in both not documenting a physical examination and not maintaining a medical file on her husband. *See infra* Discussion.

Pill Count

Respondent argues that all of the pill counts were inaccurate. Resp Exceptions, at 27. She states, “For example, the agents failed to recognize the different dosages of the same

medication, which amounted in a larger amount of pills for the same medication (Temazepam 15 mg & 30 mg) in the first count compared to the second count.” *Id.* However, Temazepam is listed on the first count, at 30 mg, *see* GE-3, at 1, and the second count for Temazepam lists both 15 mg and 30 mg, *see* GE-14, at 11, and the different dosages on GE-14 include different corresponding National Drug Code (NDC) numbers; therefore, I see no evidence to support her claim that the counts were inaccurate. Further, even if the two dosages had been conflated during the first search, she would still have an unexplained shortage. It is also noted that Respondent argues that the Government’s Exhibit 14 is “not signed, dated or witnessed;” however, the first page of the exhibit includes a signed, dated and sworn statement of the “itemized and individually described account of evidence seized” GE-14, at 1.

Finally, Respondent contends that the investigators counted more Apap Codeine in GE-14 than in GE-3, and that “[o]nly mistakes could logically account for an increase in the same medication at the second count.” It is illogical to assume that only a mistake in the count could explain an overage. The record reflects other overages, so Respondent could have acquired additional controlled substances between the two searches. *See infra* n.30. Additionally, the reason that it is difficult to determine the cause for the overages is that Respondent’s recordkeeping was inadequate, which is also the reason why the overages and shortages are relevant to this case.

Statute of Limitations

The Respondent seeks to apply a five-year statute of limitations to this proceeding and cites 18 U.S.C. 3282, 19 U.S.C. 1621 and 28 U.S.C. 2462.*^D Resp Exceptions, at 32. However, none of these provisions apply. Prior agency decisions have long stated that neither the law nor federal regulations governing DEA administrative adjudications prescribe a statute of limitations. *See Edmund Chein, M.D.*, 72 FR 6580, 6590 n.17 (2007)(“there is no statute of limitations applicable to these proceedings, which are remedial in nature and are instituted to protect the

*^D Respondent also cites “USCA Sec. 525”, but it is unclear to which law she is referring.

public interest”); *see also Pettigrew Rexall Drugs*, 64 FR 8855, 8859 (1999). Additionally, Respondent argues that the time lapse in the investigation “does not align with the DEA being concerned with [Respondent’s] prescribing behavior or misconduct,” and she points out that she was allowed to renew her registration during the investigation. Resp Exceptions, at 33.

However, the agency has clear discretion regarding whether to bring an enforcement action, and it defies reason to construe the fact that the agency permitted Respondent to continue to prescribe during the pendency of the investigation, before giving her procedural due process, to imply that no violation occurred. *See Frank Joseph Stirlacci M.D.*, 85 FR 45,229, 45,236 (2019).

Accepting Responsibility

Respondent contends that she “clearly accepted responsibility and demonstrated remedial measures when she stopped ordering from E-Compounding pharmacies, storing controlled substance, prescribing controlled substances to family members, and self-prescribing, as well as when she closed her practice to work as a medical director for another practice without prescribing controlled substances and improving her recordkeeping to meet the proper requirements of federal and state laws” Resp Exceptions, at 2. Respondent presented no evidence establishing these remedial measures on the record and did not testify regarding the allegations. Furthermore, even in making these written statements, Respondent has not accepted responsibility for her actions. Even if I fully considered her post-hearing, off-the-record statement that she “accept[s] full responsibility for being less than accurate in [her] recordkeeping duties during the time [she] was dispensing to patients,” her recordkeeping violations were not limited to dispensing and she makes no attempt at taking responsibility for her other violations of law. Furthermore, she passes blame on DEA for not telling her how to comply with recordkeeping requirements, *id.* at 18, and she passes blame on the pharmacy for filling her “office use” prescriptions, *id.* at 26. I find that there is no adequate or credible acceptance of responsibility on the record and I further find that the ALJ appropriately considered Respondent’s lack of acceptance of responsibility in his sanction recommendation.

See Pharmacy Doctors Enterprises, Inc. v. Drug Enf't Admin., 789 F. App'x 724, 732 (2019); *Jones Total Health Care Pharmacy, LLC v. Drug Enf't Admin.*, 881 F.3d 823, 830 (11th Cir. 2018) (citing *MacKay v. Drug Enf't Admin.*, 664 F.3d 808, 820 (10th Cir. 2011) (“The DEA may properly consider whether a physician admits fault in determining if the physician’s registration should be revoked.”)); *see also Jeffrey Stein, M.D.*, 84 FR 46,968, 46,972-73 (2019) (unequivocal acceptance of responsibility); *Jayam Krishna-Iyer, M.D.*, 74 FR 459, 463 (2009) (collecting cases).

The issue before the Administrator is whether the record as a whole establishes that it would be inconsistent with the public interest under 21 U.S.C. 824(a)(4) and 823(f) to allow Respondent to retain her DEA COR and/or to grant her pending application.

The decision below is based on my consideration of the entire Administrative Record, including all of the testimony, admitted exhibits, and the oral and written arguments of counsel. I adopt the ALJ’s Recommended Decision with noted modifications.

Paul A. Dean, Esq. and John E. Beerbower, Esq., for the Government

Ester Mark, M.D., for the Respondent

RECOMMENDED RULINGS, FINDINGS OF FACT, CONCLUSIONS OF LAW, AND DECISION OF THE ADMINISTRATIVE LAW JUDGE

THE ALLEGATIONS

1. On March 13, 2014, DEA investigators served an Administrative Inspection Warrant (“AIW”) at Respondent’s then-registered address: 22391 Sunbrook, Mission Viejo, California 92692. Then on June 13, 2014, DEA investigators, in conjunction with investigators from the California Medical Board, (“Medical Board”)*^E executed a search warrant at the same location. On both dates, investigators found a variety of controlled substances located on open shelves, on top of the office copier, and in unlocked glass cabinets. In addition, on June 13, 2014, the investigators also found marijuana in Respondent’s home. Respondent’s COR did not authorize

*^E The Medical Board also assisted in the execution of the March 13, 2014 AIW.

her to possess marijuana. Further, investigators could not lock the door to Respondent's office. None of the controlled substances found at Respondent's registered address were secured in a locked cabinet, in violation of 21 CFR 1301.75(a) and (b). ALJ-1, at 2, para. 3, 5.

2. In association with the March 13, 2014 AIW, investigators attempted to conduct a physical inventory of the controlled substances located at Respondent's registered location. The investigators were not able to locate an initial inventory or a biennial inventory. The only records Respondent was able to provide were invoices from May 23, 2013, through March 13, 2014. Therefore, Respondent did not maintain complete and accurate records, including receiving records (such as DEA 222 Forms), dispensing logs, or the required inventories, in violation of state and federal law. In addition, at the time of the execution of the search warrant on June 13, 2014, Respondent did not maintain any of these required records. ALJ-1, at 2, para. 4, 5.

3. There were differences in the inventories of the controlled substances found in Respondent's office on March 13, 2014, and June 13, 2014. Specifically, the following items were missing without any record of their dispensation: 25 Alprazolam 1 mg, 30 count bottles; 10 Clonazepam 1 mg, 30 count bottles; 3 Diethylpropion HCl 25 mg, 28 count bottles; 3 Hydrocodone 10/325 mg, 30 count bottles; 2 Hydrocodone/IBU 7.5/200 mg, 30 count bottles; 64 Phentermine 37.5 mg, 30 count bottles; 3 Temazepam 30 mg, 30 count bottles; 12 Zolpidem 10 mg, 30 count bottles; and 10 vials of various anabolic steroid and testosterone-related products. Respondent was unable to account for the discrepancies through the production of required dispensing logs. ALJ-1, at 3, para. 6.

4. During the search on June 13, 2014, investigators found prescription bottles in Respondent's possession bearing the names of at least five other individuals. The bottles were located on her office desk, in violation of the California Health and Safety Code § 11350, and 21 CFR 1306.04. Specifically, the following controlled substances issued to other individuals were discovered: Alprazolam 2 mg (90 dosage units) issued to L.F.; Testosterone cypionate (1 bottle

2500 mg/10 mL) issued to B.S.; Testosterone cypionate (1 bottle 1000 mg/10 mL) issued to B.S.; Testosterone cypionate (1 vial 200 mg) issued to B.S.; Testosterone cypionate (3 bottles 2500 mg/10 mL) issued to D.V.; Xanax 2 mg (15 dosage units) issued to J.W.; Testosterone cypionate (1 vial 200 mg/10 mL) issued to J.W.; and Xanax 2 mg (15 dosage units) issued to D.D. ALJ-1, at 3, para. 7.

5. Between February 16, 2010, and July 13, 2015, Respondent unlawfully issued over 75 prescriptions for controlled substances that were for other than a legitimate medical purpose or outside the usual course of professional practice. Specifically, Respondent illegally prescribed controlled substances to herself and to her current husband, S.P., as set forth below:

a. Between February 16, 2010, and November 29, 2012, Respondent unlawfully issued at least 40 prescriptions to herself for controlled substances “for office use” in violation of the California Health and Safety Code § 11170 and 21 CFR 1306.04(a) and (b). ALJ-1, at 3, para. 8(a).

b. Respondent issued at least 35 prescriptions to her husband, S.P., outside the usual course of professional practice or for other than legitimate medical purposes in violation of state and federal law. From April 21, 2012, through June 12, 2014, Respondent issued prescriptions to S.P. without any documentation or examination. California regulations explicitly provide that the failure to medically evaluate a patient to determine his or her need for a controlled substance before prescribing a controlled substance, or to document such an evaluation in the patient’s records, means that the physician is not prescribing in the usual course of professional practice. Respondent’s actions violated state and federal law. ALJ-1, at 3-4, para. 8(b).

6. Respondent also engaged in other conduct which may threaten the public health and safety in violation of 21 U.S.C. 823(f)(5). Specifically, Respondent displayed a lack of candor during DEA’s investigation. In March 2014, Respondent told DEA investigators that patient files they requested “were not there,” and that at least some of the missing files were at a location in Lake Forest, California, for which she did not know the address. During subsequent

questioning, Respondent again stated that the charts requested by the DEA were at another location, but she did not know the location. Respondent also stated that the dispensing log that DEA requested was actually with the missing charts. In fact, the charts in question, and the dispensing log, did not exist. Then in June 2014, Respondent told a Medical Board investigator that she did not know who owned the marijuana that was found in a suitcase in the garage of her registered location. She made this statement despite the fact that additional stashes of marijuana and large amounts of cash were discovered throughout her registered location, and she and her husband were the only individuals who lived there. ALJ-1, at 4, para. 9.

WITNESSES

I. The Government's Witnesses

The Government presented its case through the testimony of five witnesses. First, the Government presented the testimony of a Diversion Investigator (hereinafter, DI 1). Tr. 13-61, 317-319. DI 1 has been a Diversion Investigator for 14 years, and has been assigned to the DEA office in Riverside, California, for the past 7 years. *Id.* at 14. DI 1 provided testimony concerning her training and duties as a Diversion Investigator. *Id.* at 14-17. DI 1 began an investigation of Respondent after the DEA had received a complaint. *Id.* at 18. In the initial stages of the investigation, DI 1 conducted a search of the California prescription monitoring program ("PMP"), called CURES. *Id.* That search revealed that Respondent had written prescriptions to herself and to her family members. *Id.* DI 1 then contacted the Medical Board and requested the issuance of an Administrative Inspection Warrant ("AIW"). *Id.* at 19. Subsequently, DI 1 participated in the execution of the AIW, and later the execution of a search warrant at Respondent's home, which also doubled as her registered location. *Id.* at 19, 37. DI 1 provided testimony concerning the execution of the AIW and the search warrant and what was requested of Respondent, and what was found at Respondent's home during the AIW and the search warrant. *Id.* at 19.

I find DI 1's testimony to be thorough, detailed, and internally consistent. Therefore, I merit it as credible in this Recommended Decision.

Second, the Government presented the testimony of a Special Agent of the California Department of Justice (hereinafter, SA 1). *Id.* at 63-101. SA 1 has held her current position since July 2014. *Id.* at 63. Prior to her current position, and during the relevant period of this case, SA 1 had been an investigator for the Medical Board from October 2009 until July 2014. *Id.* SA 1 received specialized training to serve as an investigator for the Medical Board. *Id.* at 64. SA 1 provided testimony concerning her participation with the DEA during the execution of the AIW and the search warrant. *Id.* at 65-68, 80-99. SA 1 also testified concerning an interview she conducted with Respondent on April 4, 2014. *Id.* at 69-80.

I find SA 1's testimony to be thorough and internally consistent. Therefore, I merit SA 1's testimony as credible in this Recommended Decision.

The third Government witness was a Special Agent with the California Department of Justice (hereinafter, SA 2). *Id.* at 103-19. SA 2 had been a Special Agent for three years, and prior to that he served as an investigator with the Medical Board. *Id.* at 104. SA 2 provided testimony concerning his participation in the execution of the AIW as well as the execution of the search warrant. *Id.* at 105-12, 116-17. SA 2 also testified concerning records he obtained from the E-Compounding Pharmacy and other pharmacies concerning prescriptions Respondent had written. *Id.* at 113-16.

I find SA 2's testimony to be thorough and internally consistent. Therefore, I merit SA 2's testimony as credible in this Recommended Decision.

The fourth witness the Government called to testify was a second Diversion Investigator (hereinafter, DI 2). *Id.* at 120-36, 321. DI 2 has been a diversion investigator for five years, after having been employed by DEA in other capacities. *Id.* at 120-21. DI 2 attended 12 weeks of diversion investigator training at Quantico, Virginia, following that training he was assigned to the DEA office in Riverside, California. *Id.* at 121. DI 2 provided testimony concerning his

participation in the execution of the AIW, noting what he observed and statements made by Respondent during the AIW. *Id.* at 121-30. He also testified concerning his participation in the execution of the search warrant, noting what he observed and statements made by Respondent during the search. *Id.* at 130-32.

I find DI 2's testimony to be thorough and internally consistent. Therefore, I merit DI 2's testimony as credible in this Recommended Decision.

Finally, the Government presented the testimony of Dr. Timothy Munzing, M.D. (hereinafter, Dr. Munzing). *Id.* at 158-295. Dr. Munzing is currently a family physician and the Director of the Family Medicine Residency Program at Kaiser Permanente Orange County. *Id.* at 158-59. Government Exhibit 9 is a copy of Dr. Munzing's curriculum vitae. *Id.* at 163-64. Dr. Munzing obtained his medical degree from the UCLA School of Medicine in 1982, followed by a three-year residency in family medicine. *Id.* at 159. Dr. Munzing is licensed to practice medicine in California and he is board-certified in family medicine. *Id.* at 159, 163. Dr. Munzing is a full clinical professor at UC-Irvine College of Medicine, where he has taught medical students for 25 years. *Id.* at 160-61, 166. Dr. Munzing was accepted as an expert, without objection, in the field of "primary care and family medicine, pain management and prescribing controlled substances with respect to the standard of care in the state of California." *Id.* at 171.

Dr. Munzing testified about the standard of care in California. *Id.* at 174-80. He specifically testified that a doctor who does not maintain a medical record of his or her patient violates the standard of care in California by issuing a prescription for a controlled substance to that patient. *Id.* at 176, 178-80. Thus, the prescriptions Respondent wrote to her husband, without having a medical chart for her husband, fell outside the standard of care. *Id.* at 182-99. Dr. Munzing also testified that the California standard of care provides that a doctor cannot self-prescribe or issue prescriptions for office use. *Id.* at 200-01, 229, 289. Thus, the prescriptions

that Respondent wrote to herself or for office use also fell outside the standard of care. *Id.* at 203-23, 225-28, 243-44.

I find Dr. Munzing's testimony to be thorough, detailed, and internally consistent.*^F

Therefore, I merit it as credible in this Recommended Decision.

II. The Respondent's Witness

Respondent presented her case through her own testimony, which she limited to the identification of two documents. *Id.* at 302-13. Through her testimony, Respondent offered a copy of her dispensing log that was seized during the search of her home on June 13, 2014. *Id.* at 306; RE-1. Respondent also offered a copy of her Florida medical license, which had expired in January 2017. Tr. 307; RE-2.

While Respondent's testimony laid the foundation for the admission of her two exhibits, on cross-examination her answers were somewhat combative, confusing, and evasive. For example, Respondent was asked in several different ways whether she had provided DEA with her dispensing log in March 2014, and she avoided actually answering the question, finally stating "I don't recall." Tr. 309-12. Respondent also clearly distorted the facts when she testified that Respondent's Exhibit 1 concerned prescriptions between March 13, 2014, and June 13, 2014, because the first entry on the dispensing log is January 21, 2014. *Id.* at. 310-11; RE-1.*^G Combativeness, confusion, and evasiveness tend to undermine the credibility of a witness, and they did with respect to Respondent's testimony that she was asked no questions by DEA on June 13, 2014. Tr. 312.

*^F [Respondent questioned Dr. Munzing's credibility in her Exceptions. Resp Exceptions, at 31. The fact that Dr. Munzing has testified for DEA in previous cases does not alter the finding that his testimony in this case was credible and un rebutted. Most of the allegations in this case were proven by Respondent's recordkeeping failures, and were not reliant solely on Dr. Munzing's testimony regarding the standard of care. Her prescribing to her husband lacked any documentation at all on which to assess the legitimacy of those prescriptions. She alleged that the "Government did not provide sufficient evidence for the expert witness to conclude if [Respondent's] prescribing [was] unlawful," *id.*, but her failure to maintain records resulted in no evidence to conclude that her prescribing was *lawful* and that failure by itself violated state law and the standard of care. I reject her Exceptions as to Dr. Munzing's credibility and the basis of his opinions.]

*^G [Respondent took exception to this description of her statement, claiming that the earlier date coverage shows that the log "is actually more inclusive." Resp Exceptions, at 20. However, she misses the ALJ's point that because the logs were created at an earlier date, they should have been made available to DEA in March of 2014.]

When Respondent was asked if investigators requested a dispensing log on June 13, 2014, Respondent answered, “[N]obody asked me anything. They broke down my door, I was detained. So there was no – nobody asked me anything.” *Id.* at 312. DI 1, however, testified that she did ask Respondent for a dispensing log on that date. *Id.* at 39. DI 2 also believed that the DEA asked Respondent for her dispensing log on that date. *Id.* at 132. SA 1 also testified that Respondent had been asked questions about the location of the patient chart for Respondent’s husband, and Respondent stated that the chart was in pieces around the house. *Id.* at 91. Thus, while I find Respondent’s testimony credible on issues related to laying the foundation for the admission of Respondent’s Exhibits 1 and 2, I do not find it credible concerning whether she was asked any relevant questions during the search of her home on June 13, 2014.

The factual findings below are based on a preponderance of the evidence, including the detailed, credible, and competent testimony of the aforementioned witnesses, the exhibits entered into evidence, and the record before me.

THE FACTS

I. Stipulations

The parties agreed to 14 stipulations (“Stip.”), which are accepted as facts in these proceedings:

1. Respondent is registered with the DEA as a practitioner to handle Controlled Substances in Schedules II-V under DEA COR #BM5370123 at Beautymark Wellness Center, 361 Hospital Road, Suite 324, Newport Beach, California 92663. This DEA COR is due to expire by its terms on January 31, 2018. ALJ-9, 24, 25.
2. On August 5, 2015, Respondent sought to transfer her DEA registration to 8409 N. Military Trail, Suite 126, West Palm Beach, Florida 33410. DEA assigned control number W15069021C to Respondent’s pending application for transfer. ALJ-9, 24, 25.
3. Respondent is licensed to practice medicine in California under license number 55272. Respondent’s California medical license is due to expire May 31, 2019. ALJ-9, 24, 25.

4. On or about September 26, 2013, Respondent changed her DEA registration address to Beautymark Wellness Center, 22391 Sunbook (sic), Mission Viejo, California. On or about August 19, 2014, Respondent changed her DEA registration address to 361 Hospital Road, Suite 324, Newport Beach, California. ALJ-9, 24, 25.
5. On or about March 13, 2014, law enforcement officials (including DEA investigators) served an administrative inspection warrant (AIW) at Respondent's then-registered address and residence, Beautymark Wellness Center, 22391 Sunbrook, Mission Viejo, California 92692. ALJ-9, 24, 25.
6. On or about June 13, 2014, law enforcement officials (including DEA investigators) executed a search warrant at Respondent's then-registered address and residence, Beautymark Wellness Center, 22391 Sunbrook, Mission Viejo, California 92692. ALJ-9, 24, 25.
7. DEA lists Alprazolam (Xanax) as a Schedule IV controlled substance. ALJ-44; Tr. 6.
8. DEA lists Clonazepam (Klonopin) as a Schedule IV controlled substance. ALJ-44; Tr. 6.
9. DEA lists Diethylpropion hydrochloride as a Schedule IV controlled substance. ALJ-44; Tr. 6.
10. During the events at issue, DEA listed Hydrocodone as a Schedule III controlled substance. ALJ-44; Tr. 6.
11. DEA lists Phentermine as a Schedule IV controlled substance. ALJ-44; Tr. 6.
12. DEA lists Temazepam as Schedule IV controlled substance. ALJ-44; Tr. 6.
13. DEA lists Testosterone as a Schedule III controlled substance. ALJ-44; Tr. 6.
14. DEA lists Zolpidem as a Schedule IV controlled substance. ALJ-44; Tr. 6.

II. Findings of Fact

Administrative Inspection Warrant ("AIW")

1. DEA and Medical Board personnel participated in the execution of the AIW on March 13, 2014, at Respondent's home. Tr. 20, 65, 94.

2. DI 1, SA 1, SA 2, and DI 2 participated in the execution of the AIW on March 13, 2014, at Respondent's home. *Id.* at 19, 65, 105, 121-22.
3. During the execution of the AIW, Respondent identified the area of her home that she used as her office. *Id.* at 22.
4. During the execution of the AIW, multiple bottles of controlled substances were found on the desk, on the shelf, and on the printer in Respondent's office. *Id.* at 22, 66, 105-06, 123.
5. The controlled substances found in Respondent's office were not secured in any way, and there did not appear to be any place to secure them in her office. *Id.* at 22, 66, 106, 124.
6. Some of the controlled substances found in Respondent's home during the AIW were in prescription bottles that bore labels from commercial pharmacies, indicating that the prescriptions were for individuals who did not live in Respondent's home. *Id.* at 123-24.
7. DI 1 did not notice a lock on Respondent's door. Tr. 39. SA 1 does not believe there was a lock on Respondent's office door.¹ *Id.* at 66-67.
8. The DEA investigators requested that Respondent purchase some type of safe in which to store the controlled substances,² and Respondent indicated that one would be purchased that day. *Id.* at 23, 36, 130.
9. DEA investigators took an inventory of the controlled substances they found in Respondent's office. *Id.* at 25, 125. Government Exhibit 3 is a copy of that physical inventory. *Id.* at 25-26, 125.
10. DEA investigators asked Respondent to provide them with patient charts during the execution of the AIW. *Id.* at 21, 54, 127.

¹ DI 2 testified that there may have been a lock on the door, but the door was wide open. Tr. 124.

² DI 1 testified that she told Respondent she needed to purchase a safe to store controlled substances. *Id.* at 23, 35. I asked DI 1 at the hearing why she advised Respondent to obtain a safe when the regulation only refers to a "cabinet." *Id.* at 51. DI 1 then acknowledged that DEA regulations do not specifically mandate that controlled substances be stored in a safe. *Id.* at 51. Thus, the fact that Respondent did not purchase a safe to store her controlled substances does not by itself necessitate a finding that Respondent violated 21 CFR 1301.75(b). I note, however, that DEA regulations do include heightened security for thiafentanil, carfentanil, etorphine hydrochloride, and diprenorphine. Those controlled substances must be kept "in a safe or steel cabinet equivalent to a U.S. Government Class V security container." 21 CFR 1301.75(e). Those substances, however, are not involved in this case.

11. Some patient charts were located in Respondent's garage, a location where the investigators looked while trying to locate the charts of specific patients. *Id.* at 66, 95-96, 106.
12. Respondent did not provide all of the patient records requested by DEA during the AIW. Tr. 23, 54. Respondent told the DEA investigators that the patient records were at a storage facility in Lake Forest, California, but she did not know the address of the facility or where it was located.³ *Id.* at 23-24, 54, 56, 67, 127-28, 135-36.
13. Respondent never provided to DEA copies of all of the patient charts that DEA had requested. *Id.* at 31-32, 35, 54, 128.
14. The DEA investigators asked Respondent for her dispensing logs and Respondent told them that her dispensing logs were with her patient charts in the storage facility. Tr. 24, 54, 128. The storage facility was at her mother-in-law's house. *Id.* at 55.
15. The DEA investigators asked Respondent to provide them with an initial inventory and a biennial inventory, but Respondent did not provide either of them to the DEA. *Id.* at 24.
16. Without an initial or biennial inventory it is not possible to conduct a reasonable inventory of controlled substances. *Id.* at 25.
17. The DEA investigators asked Respondent for copies of invoices for controlled substances that she had received and Respondent provided some. *Id.* at 28. Government Exhibit 2 contains copies of the invoices Respondent provided. *Id.* at 29-30.
18. Respondent should have had more invoices than she provided to the DEA investigators because the invoices she provided did not account for all the controlled substances that were found in her office on March 13, 2014. *Id.* at 31.

³ DI 1 attributed these statements to Respondent. Tr. 23-24, 54, 56. SA 1 testified that she asked Respondent about the missing charts and she deferred to her husband, who stated that the charts might be in a storage facility. Tr. 67. There is no evidence, however, that Respondent corrected her husband's statement. *[See also GE-12, at 82-83. Respondent told the state investigator that the dispensing logs and charts were all in her garage during the sworn interview and seemed reluctant to speak about her mother-in-law's house or to confirm where it was. *Id.* at 27-28]

19. An invoice for controlled substances needs to be kept for two years. *Id.* at 51. DEA does not know if any of the controlled substances found in Respondent's home were more than two years old. *Id.*

20. At the conclusion of the execution of the AIW, DI 1 had a discussion with Respondent concerning the missing patient charts and dispensing logs, as well as the security of controlled substances. *Id.* at 35. Respondent was informed that controlled substances needed to be locked in a cabinet or safe. *Id.* at 35, 129-30.

21. As an investigator for the Medical Board, SA 1 was concerned about how Respondent was storing her controlled substances, and on March 13, 2014, SA 1 informed Respondent that controlled substances needed to be locked-up. *Id.* at 67, 94.

22. During the AIW, Respondent told SA 1 that she ordered prescriptions in her own name for office use and that she dispensed them to her patients. *Id.* at 68.

23. During the AIW, it was determined that only two individuals lived in Respondent's home; those individuals were Respondent and her husband, S.P. *Id.* at 107-08.

24. During the AIW, three pistols were found in Respondent's home, two of them belonged to Respondent, but the ownership of the third was undetermined. *Id.* at 109.

25. During the AIW, SA 1 asked Respondent if she would be willing to be interviewed regarding the Medical Board case that SA 1 was investigating. *Id.* at 68-69.

Interview

26. Government Exhibit 12 is a copy of the transcript of the interview SA 1 conducted with Respondent on April 4, 2014. *Id.* at 69. During the interview, Respondent was represented by counsel and Respondent was under oath. *Id.* at 68-69.

27. During the interview, Respondent stated that she stored some office equipment and furniture in her mother-in-law's garage, but all of her patient charts were in her own garage. Tr. 71, 78; GE-12, at 28, 82-84.

28. During the interview, Respondent stated that she had prescribed an antibiotic to herself. Tr. 73; GE-12, at 55. Respondent also said that she prescribed testosterone in her own name, but that the medication was for office use. *Id.*

29. During the interview, Respondent also stated that she prescribed phentermine and alprazolam to herself *[for office use.]* Tr. 74; GE-12, at 60.

30. During the interview, Respondent explained that she would often dispense medication to her patients if they were using it for the first time. Tr. 74; GE-12, at 62. Respondent also stated that if the medication worked well for the patient she would then possibly write the patient a prescription for the medicine. *Id.*

31. During the interview, SA 1 had a discussion with Respondent concerning the fact that when Respondent dispensed controlled substances to patients those prescriptions would not show up in the PMP report. Tr. 74-75; GE-12, at 63. SA 1 also explained to Respondent that a patient could be placed in danger because the prescriptions Respondent provided to patients would not be in the PMP system. *Id.* In response, Respondent indicated that she did not see that to be a problem.⁴ *Id.*

32. During the interview, SA 1 asked Respondent if she had taken any steps to secure the controlled substances in her home, and Respondent indicated that she had not. Tr. 77; GE-12, at 77-78.

Search Warrant

33. After the interview, SA 1 believed that she had sufficient probable cause to draft a search warrant for Respondent's residence. Tr. 80. After drafting the search warrant, SA 1 had it signed by a judge. Tr. 81.

* [I agree with Respondent that this finding of fact as stated could be misleading, and that in her interview, she implied that these prescriptions were also for office use, so I have changed it accordingly. See Resp Exceptions, at 9 (citing GE-12, at 60).]

⁴ See also Tr. 202 (Dr. Munzing testifying that there is a potential of placing the patient at risk when a doctor dispenses controlled substances to a patient without entering that prescription in the PMP system).

34. DI 1, SA 1, SA 2, and DI 2 returned to Respondent's home on June 13, 2014, when the Medical Board executed a search warrant of Respondent's office and residence. *Id.* at 38, 82, 110, 129.

35. Government Exhibit 5 consists of photographs taken at Respondent's home on June 13, 2014, when the search warrant was executed. *Id.* at 82. Some of the bottles depicted in Government Exhibit 5 are bottles of controlled substances. *Id.* at 83.

36. The condition of Respondent's office on June 13, 2014, looked the same as it did on March 13, 2014, with controlled substances being found all over the office area. *Id.* at 38, 111, 130-31. There was no safe in Respondent's office on June 13, 2014. *Id.* at 38-39, 131. A bottle of controlled substances was also found in Respondent's kitchen. *Id.* at 41, 58-59.

37. Some of the controlled substances found in Respondent's home on June 13, 2014, were in prescription bottles that bore labels from commercial pharmacies, indicating that the prescriptions were for individuals who did not live in Respondent's home. *Id.* at 40, 53-54; GE-14, at 11-12.

38. On June 13, 2014, DEA asked Respondent for her dispensing log.⁵ Tr. 39, 132.

39. On June 13, 2014, DEA took another inventory of the controlled substances that were found in Respondent's home and that inventory revealed a significant difference from the March 13, 2014 inventory. *Id.* at 40-41, 131-32. The June 13, 2014 inventory showed that Respondent was missing controlled substances that had been present on March 13, 2014. *Id.* at 41.

40. On June 13, 2014, marijuana was discovered in a suitcase in Respondent's garage. Tr. 45, 111. Marijuana was also found in Respondent's kitchen and bedroom. *Id.* at 112, 132. Marijuana is a Schedule I controlled substance. *Id.* at 46.

⁵ Both DI 1 and DI 2 testified that Respondent was asked about her dispensing log at the time the search warrant was executed on June 13, 2014, and that Respondent did not provide it. Tr. 39, 132. Respondent, however, was in no position to "provide" anything during the search, she was handcuffed. Tr. 110; *see also* Tr. 312 (Respondent testifying that she was detained at the time). The search, however, resulted in locating a dispensing log in Respondent's home office. GE-14, at 9; RE-1.

41. Government Exhibit 10 contains photographs taken at Respondent's home during the execution of the search warrant that depict marijuana that was found there. *Id.* at 84.
42. On June 13, 2014, SA 1 asked both Respondent and her husband whether either of them had a valid recommendation for medical marijuana. *Id.* at 90. Respondent told SA 1 that her recommendation had expired, and Respondent's husband said that his had probably expired as well. *Id.*
43. Respondent was questioned about the marijuana and she denied knowledge of how it came to be in her house. *Id.* at 91.
44. Government Exhibit 11 contains photographs taken at Respondent's home during the execution of the search warrant that depict the patient charts that were found there. *Id.* at 86.
45. SA 1 questioned Respondent about the location of missing patient charts, to include the chart for Respondent's husband. *Id.* at 91. Respondent stated that her husband's chart was in pieces around the house, but she had no explanation for where two other missing charts were located. *Id.* Respondent, however, stated that all of her charts were in her home. *Id.* at 92.
46. During the June 13, 2014 search of Respondent's home, the investigators found \$26,100 in cash. *Id.* at 91.
47. Government Exhibit 14 is the search warrant return that SA 1 filed with the Orange County Superior Court after the search warrant was executed, along with property receipts of the items that were seized from Respondent's home during the search. *Id.* at 87-88. Government Exhibit 14 also contains a full accounting of the controlled substances found within Respondent's home on June 13, 2014. *Id.* at 89.

Prescriptions

48. Government Exhibit 13 is a copy of a PMP report that the DEA obtained from the California Department of Justice concerning prescriptions written by Respondent. *Id.* at 32-34. The inclusive dates of the PMP report are February 27, 2014 through February 27, 2017. GE-13, at 1.

49. Government Exhibit 7 contains copies of records from the E-Compounding Pharmacy concerning prescriptions written by Respondent for herself. Tr. 113.

50. Government Exhibit 8 contains copies of prescriptions and related documents concerning prescriptions that Respondent wrote for her husband, S.P., that were obtained from various pharmacies. *Id.* at 115-16.

51. The standard of care in California requires that during an initial visit with a patient a doctor must: obtain a history from the patient concerning the patient's current complaint; review the symptoms of the patient's current complaint; determine the cause of the patient's current condition and how long the patient has had the condition; obtain a medical history from the patient; determine what medications the patient has been taking, both prescriptions and over-the-counter medications; determine the patient's drug and alcohol history; perform a general overall physical examination of the patient, and a detailed examination of the area of the patient's body that is the focus of the current complaint; determine whether any laboratory or other type of testing is needed; determine whether a referral to a specialist is needed; advise the patient of the risks and benefits of prescribed medications; and document what had been performed. *Id.* at 174-76.

52. The standard of care in California requires that during a follow-up visit with a patient that a doctor must: get an updated history to determine if there have been changes in the patient's condition; determine whether the treatment is working; determine current drug and alcohol usage; and monitor the patient through use of PMP reports and urine screening. *Id.* at 178-79.

53. The standard of care in California requires that a doctor have a medical record for a patient to whom prescriptions are issued. *Id.* at 180.

54. The standard of care in California requires that a doctor include the following items in a patient's medical record: history, exam, consent, diagnosis, management plan; results of laboratory testing; results of imaging studies; prescriptions issued; PMP reports run for the patient; and/or results of urine screening. *Id.* at 179-80.

55. Assuming there is no medical record for S.P., the 27 prescriptions⁶ for controlled substances written by Respondent to S.P. between April 21, 2012 and June 12, 2014, contained in Government Exhibit 8, are outside the standard of care in California. *Id.* at 182-99; GE-8, at 3, 12 (2 prescriptions), 28-29, 34, 38-39, 76, 78, 80, 82, 83, 85, 87, 89, 91, 93, 95, 97, 99, 111, 113, 125, 128, 130, 132-34.

56. The prescriptions in Government Exhibit 8 are outside the standard of care because of the absence of a medical record that documents that the doctor has performed the type of medical examination that must be performed before the doctor issues a prescription. *Id.* at 184.

57. The California standard of care and California Health and Safety Code § 11170 provide that a doctor may not self-prescribe controlled substances. Tr. 134, 200. In addition, the American Medical Association Code of Ethics says that a doctor cannot self-prescribe or prescribe to close relatives. *Id.* at 200.

58. Unless a California doctor follows the proper procedures for obtaining a controlled substance “for office use,” it is outside the standard of care in California as well as the course of professional practice for a doctor to write a prescription for a controlled substance “for office use.” *Id.* at 200-01, 229, 289.

59. A prescription for 300, 450, or 600 tablets of phentermine would be a very large quantity if the prescription was for office use. Tr. 207, 212-13, 247. If a patient needed that much phentermine, the patient could be issued a prescription that would then be reported to the PMP system. Tr. 207, 210-11, 215, 242. A prescription written for office use of such large quantity of phentermine would be outside the standard of care in California. *Id.* at 247.

60. A prescription for office use of 300 tablets of Ambien would be an excessive number of tablets and outside the standard of care in California. *Id.* at 245-46; GE-7, at 35.

⁶ The Government presented testimony concerning 32 prescriptions that Respondent issued to S.P., but 5 of those prescriptions fell outside the date range contained in the OSC. Tr. 182-86, 194; ALJ-1, at 3, para. 8(b); GE-8, at 10, 27, 31 and 37, 67 (2 prescriptions).

61. Respondent wrote four prescriptions for hydrocodone for office use. GE-7, at 12, 13, 36 (2 prescriptions). Hydrocodone should not be dispensed from the office because it would not provide immediate relief, but might cause the patient to become drowsy. Tr. 241-42. Thus, prescribing hydrocodone for office use is outside the standard of care in California. *Id.* at 242.

62. The 69 prescriptions for controlled substances written by Respondent to herself, contained in Government Exhibit 7, are outside the standard of care in California. Tr. 203-23, 225-28, 243-44; GE-7, at 5, 23, 25, 26, 29, 31 (4 prescriptions), 33, 34, 37, 40 (2 prescriptions), 41 (4 prescriptions), 42-45, 47, 49, 51, 52, 54, 57, 59-61, 63 (2 prescriptions), 64, 67-70, 72-74, 86, 87, 89, 95 (4 prescriptions), 99, 101, 107, 110, 112-14, 122, 130, 133, 135, 139, 140 (3 prescriptions), 153 (2 prescriptions), 158, 169, 179 (2 prescriptions).

63. Four prescriptions that Respondent wrote to herself for controlled substances also included dosing instructions. Tr. 226-28; GE-7, at 40 (2 prescriptions), 47, 158. Dosing instructions on a prescription would be inconsistent with a prescription issued for office use because dosing instructions would be determined at the time the medication was prescribed to a patient, not when it was being ordered for the office. Tr. 226.

64. Seven prescriptions that Respondent wrote for controlled substances contain no patient name, nor do they indicate that they were for office use. Tr. 224-25; GE-7, at 16, 22, 24, 28 (3 prescriptions), 30. These seven prescriptions were issued outside the California standard of care because there is no listed patient, nor is there any stated reason for any of the prescriptions. Tr. 224-25.

65. Twenty-four^{*1} prescriptions that Respondent wrote for controlled substances contain no patient name but they were written for office use. Tr. 228-37; GE-7, at 146, 150, 152 (3 prescriptions), 156 (1 prescription), 160 (3 prescriptions), 162 (2 prescriptions), 166 (2 prescriptions), 171 (2 prescriptions), 173, 175, 177 (2 prescriptions), 178 (5 prescriptions).

^{*1} [There was one additional prescription between GE-7, at 156 and 160 that appeared to be neglected in the final count in the RD.]

These 24 prescriptions were issued outside the California standard of care because Respondent did not follow the proper procedures for ordering controlled substances for office use. Tr. 229.

66. Seventy prescriptions that Respondent wrote to herself for controlled substances contain a notation that the prescription was for office use. *Id.* at 237-66; GE-7, at 4, 6-15, 17-21, 27, 32, 35, 36 (3 prescriptions), 38, 39, 46, 50, 53, 55, 56, 58, 62, 65, 71, 75, 80 (4 prescriptions), 84, 85, 90, 91, 93, 96 (2 prescriptions), 97, 102, 103, 105, 108, 115 (3 prescriptions), 117 (2 prescriptions), 119, 120 (3 prescriptions), 123, 126, 128, 131, 137, 142, 144, 148 (4 prescriptions). These 70 prescriptions were issued outside the California standard of care because Respondent did not follow the proper procedures for ordering controlled substances for office use. Tr. 250.

67. Respondent wrote two prescriptions for controlled substances where she listed the patient's name as "office use." *Id.* at 266-67; GE-7, at 48, 164. These two prescriptions were issued outside the California standard of care because Respondent did not follow the proper procedures for ordering controlled substances for office use. Tr. 200-01, 250.

ANALYSIS

To revoke a respondent's registration, the Government must prove, by a preponderance of the evidence, that the regulatory requirements for revocation are satisfied. *Steadman v. SEC*, 450 U.S. 91, 100-02 (1981); 21 CFR 1301.44(e). Under 21 U.S.C. 824(a)(4), the DEA may revoke a registrant's COR if the registrant acted in a way that renders continued registration "inconsistent with the public interest." The DEA considers the following five factors to determine whether continued registration is in the public interest:

- (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
- (2) The [registrant's] experience in dispensing, or conducting research with respect to controlled substances.
- (3) The [registrant's] conviction record under Federal or State laws relating to

the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

21 U.S.C. 823(f).

These public interest factors are considered separately. *See Robert A. Leslie, M.D.*, 68 FR 15,227, 15,230 (2003). Each factor is weighed on a case-by-case basis. *Morall v. DEA*, 412 F.3d 165, 173-74 (D.C. Cir. 2005). Any one factor, or combination of factors, may be decisive. *David H. Gillis, M.D.*, 58 FR 37,507, 37,508 (1993). Thus, there is no need to enter findings on each of the factors. *Hoxie v. DEA*, 419 F.3d 477, 482 (6th Cir. 2005). Further, there is no requirement to consider a factor in any given level of detail. *Trawick v. DEA*, 861 F.2d 72, 76-77 (4th Cir. 1988). When deciding whether registration is in the public interest, the totality of the circumstances must be considered. *See generally Joseph Gaudio, M.D.*, 74 FR 10,083 (2009).

The Government bears the initial burden of proof and must justify revocation by a preponderance of the evidence. *Steadman*, 450 U.S. at 100-03. If the Government presents a *prima facie* case for revocation, the burden of proof shifts to the registrant to show that revocation would be inappropriate. *Med. Shoppe-Jonesborough*, 73 FR 364, 387 (2008). A registrant may prevail by successfully attacking the veracity of the Government's allegations or evidence. Alternatively, a registrant may rebut the Government's *prima facie* case for revocation by accepting responsibility for wrongful behavior and by taking remedial measures to "prevent the re-occurrence of similar acts." *Jeri Hassman, M.D.*, 75 FR 8194, 8236 (2010). In addition, when assessing the appropriateness and extent of sanctioning, the DEA considers the egregiousness of the offenses and the DEA's interest in specific and general deterrence. *David A. Ruben, M.D.*, 78 FR 38,363, 38,385 (2013).

I. The Government's Position

The Government filed its Post-Hearing Brief on March 19, 2018.⁷ In its introduction, the Government highlighted the allegations against Respondent. ALJ-50, at 2. The Government asserts that between January 2010 and June 2014 Respondent: prescribed controlled substances to her husband, S.P., “without maintaining a patient file” for him; prescribed controlled substances to herself for “‘office use’ in order to dispense controlled substances” to patients; violated security and recordkeeping requirements; and displayed a lack of candor to DEA investigators during their investigation. *Id.* The Government requests that Respondent’s COR be revoked. *Id.*

The Government argues that its evidence is “largely uncontested and entirely un rebutted.” ALJ-50, at 12. Specifically, the Government claims that it offered un rebutted evidence under Factors Two, Four, and Five. *Id.* at 14.

Under Factors Two and Four, the Government argues that the evidence shows that Respondent “routinely prescribed controlled substances without a patient chart,” issued prescriptions for controlled substances to herself, and violated storage and recordkeeping requirements under state and federal law. ALJ-50, at 15. After citing the DEA’s prescription requirement, the Government notes that California has adopted the same requirement as set forth in 21 CFR 1306.04(a), that a prescription must be issued for a “‘legitimate medical purpose’” and in the “‘usual course of . . . professional practice.’” *Id.* (citing Cal. Health & Safety Code § 11153(a)). The Government then highlights the testimony of its expert witness, Dr. Munzing, who explained that the standard of practice in California requires a physician to “maintain a complete and accurate patient file, which documents examinations performed and treatments provided.” ALJ-50, at 15. The State of California has codified the requirement that a physician maintain complete patient files. *Id.* at 15-16 (citing Cal. Bus. & Prof. Code § 2266 and Cal. Health & Safety Code § 11190).

⁷ The Government’s Post-Hearing Brief has been marked as ALJ-50.

Looking at the prescriptions in Government's Exhibit 8, the Government argues that it is undisputed that Respondent wrote at least 50 prescriptions⁸ for controlled substances to her husband, S.P. ALJ-50, at 16. DEA investigators requested S.P.'s patient file during execution of the AIW in March 2014, and state investigators requested S.P.'s file during service of the search warrant in June 2014. *Id.* The Government then notes that during the inspection in March, Respondent told investigators that some of the requested patient records were located at a storage facility in Lake Forest, California. ALJ-50, at 4, 16. Respondent, however, claimed that she did not know the address of the facility and "did not know where it was." ALJ-50, at 4. When interviewed by a state investigator in April 2014, however, Respondent stated that all her patient files were kept at her registered address. ALJ-50, at 16. The Government notes that Respondent "never provided a patient file for Patient S.P.," investigators never found a patient file for S.P. in March or June 2014, and Respondent never produced a patient file for S.P. "in connection with this proceeding." *Id.* The Government reasons that "[t]he only logical conclusion is that [Respondent] did not keep a patient file for Patient S.P." *Id.* The Government further reasons that based on Dr. Munzing's testimony that physicians must keep complete and accurate patient records, the 50 prescriptions Respondent issued to S.P. fell below the standard of care in California and violated state law. *Id.*

Next, looking at Government Exhibit 7, the Government argues that Respondent issued at least 179 prescriptions for controlled substances to herself between January and December 2012. ALJ-50, at 17. The Government notes that many of the prescriptions in Government Exhibit 7 were issued "for office use" while others listed Respondent's name as the patient. *Id.* State and federal law prohibits a physician from prescribing controlled substances to herself. *Id.* (citing Cal. Health & Safety Code § 11170 and 21 CFR 1306.04(b)). The Government notes that the state prohibition is "categorical" and that self-prescribing controlled substances violates state law "irrespective of purpose." *Id.* n.2. Further, the Government notes that Dr. Munzing testified that

⁸ See *supra* n.6.

writing a prescription for a controlled substance in order to obtain it “for office use” is considered unprofessional practice in California. *Id.* at 17. Thus, Dr. Munzing opined that the prescriptions in Government Exhibit 7 “were issued outside of the usual course of professional practice and beneath the standard of care.” *Id.* The Government notes that Dr. Munzing’s expert opinion is un rebutted. *Id.* at 18.

The Government then discusses the recordkeeping and storage violations discovered during service of the AIW and search warrant. ALJ-50, at 18-19. The Government contends that Respondent “was not able to produce either an initial or biennial inventory of the controlled substances stored at her registered address.” ALJ-50, at 18. Additionally, Respondent never provided investigators with a dispensing log.⁹ *Id.* The Government argues that Respondent’s failure to maintain a proper inventory and a dispensing log violates state and federal recordkeeping requirements. *Id.* at 19.

With respect to the storage violation, the Government argues that Respondent ignored the attempts made by DEA and state investigators “to bring her into compliance with” DEA’s storage requirements. ALJ-50, at 19. During the inspection in March 2014, Respondent assured DEA investigators that she would promptly secure the controlled substances in her office. *Id.* At the interview in April, however, Respondent admitted that she had not done so. *Id.* When state investigators conducted the search in June, the controlled substances in her office were still

⁹ State investigators, however, seized a document entitled “Class III Meds Dispensing Log,” marked as Respondent’s Exhibit 1, during execution of the search warrant. Tr. 304-06; GE-14, at 9. The Government argues that neither Government counsel nor DEA investigators were provided with a copy of Respondent’s Exhibit 1 before the hearing. ALJ-50, at 18-19 n.4. The Government claims that “the California Medical Board declined to provide the evidence that was seized from” Respondent’s home during the search, and that the DEA failed in its attempts to obtain the release of the evidence by subpoena in state court. *Id.* I give no weight to this explanation, however, because there is no evidence in the record supporting the Government’s claim that the California Medical Board refused to disclose evidence to DEA. Statements made in post-hearing briefs are not evidence. See *Samuel Mintlow, M.D.*, 80 Fed. Reg. 3630, 3653 n.33 (2015) (concluding promises made by respondent in exceptions to the recommended decision were not in evidence and were never attested to under oath during the hearing); *Surinder Dang, M.D.*, 76 FR 51,417, 51,423 n.25 (2011) (“[S]tatements of counsel in a brief are not evidence.” (citing *INS v. Phinpathya*, 464 U.S. 183, 186 n.6 (1984))). *[Respondent implies that the Government’s failure to produce this dispensing log indicates bad faith on the part of the investigators. Resp Exceptions, at 3,19-20. The investigators testified that they had not previously seen this document and that they had asked Respondent repeatedly for her dispensing logs and she had not produced them. I do not see any indication on the record nor from the ALJ’s characterization of the investigators’ testimony that their actions were anything but honest. Ultimately, the document was admitted into evidence and the ALJ used the document to lessen the number of found discrepancies in controlled substances.]

unsecured. *Id.* The Government urges that Respondent’s “noncompliance is aggravated by her obduracy.” *Id.*

Based on the prescriptions in Government Exhibits 7 and 8, and the evidence that Respondent failed to keep complete records and properly secure controlled substances, the Government argues that “Factors Two and Four weigh heavily in favor of revoking” Respondent’s COR. ALJ-50, at 20.

Citing DEA precedent, the Government next asserts that Respondent’s lack of candor supports an “adverse finding” under Factor Five. ALJ-50, at 20. The Government claims that Respondent “attempted to mislead federal and state investigators” during their investigation by making a “series of misleading statements.” ALJ-50, at 13. For instance, the Government points to the inconsistent statements Respondent made to investigators regarding her patient file for S.P. ALJ-50, at 20. During the March inspection, Respondent stated that all patient files were located at an off-site facility. *Id.* A month later, however, she told a state investigator that all patient files were stored at her registered address. *Id.* The Government interprets these inconsistent statements as evidence of Respondent’s “deliberate effort to impede the investigation.” ALJ-50, at 21.

The Government then examines the marijuana, cash, and firearms discovered in Respondent’s home. ALJ-50, at 21. The Government notes that Respondent lacked the authority to possess marijuana, a Schedule I controlled substance, “in the course of her professional practice.” ALJ-50, at 21. Additionally, when investigators found a suitcase of marijuana in her garage, Respondent denied having any knowledge of its presence at her home. *Id.* The Government argues that this represents either a lack of candor or “a troubling situation in which [Respondent] was actually unaware of the presence of Schedule I controlled substances at her registered address.” *Id.* The Government then argues that the presence of \$26,000 in cash, firearms, and marijuana at Respondent’s registered location is “highly suspicious and raises serious concerns about [Respondent’s] ability to maintain a [COR].” *Id.*

Because Respondent failed to offer “substantive testimony” at the hearing, the Government argues that she “cannot be viewed as having accepted responsibility.” ALJ-50, at 22. By failing to accept responsibility, the Government contends that Respondent “has not met her burden” to rebut the Government’s *prima facie* case. ALJ-50, at 14. Specifically, the Government argues that Respondent’s refusal to testify demonstrates that she “knowingly violated the Controlled Substances Act.” ALJ-50, at 2. The Government requests that I draw an adverse inference from Respondent’s decision to not testify at the hearing. ALJ-50, at 2, 22. The Government reasons that “because [Respondent] failed to introduce any evidence that would rebut the Government’s evidence showing that [Respondent] violated state and federal law relating to controlled substances, such evidence does not exist.” ALJ-50, at 22 (citing *T.J. McNichol, M.D.*, 77 FR 57133, 57150 (2012)).

With respect to the DEA’s interest in specific and general deterrence, the Government contends that “[a] refusal to sanction [Respondent’s] prolonged and egregious violations here would send the wrong message to other practitioners.” ALJ-50, at 23. The Government concludes that the DEA’s interest in deterrence weighs in favor of revoking Respondent’s COR. ALJ-50, at 24.

II. The Respondent’s Position

Respondent submitted her Post-Hearing Brief on March 19, 2018.¹⁰ Much of Respondent’s position lacks evidentiary support in the Administrative Record.¹¹ Respondent opens her brief by describing events beginning in May 2013, when she “abruptly close[d] [her] office due to extreme hardship caused by a very contentious divorce that still continues . . . to

¹⁰ Respondent’s Post-Hearing Brief has been marked as ALJ-51. The Office of Administrative Law Judges received a hard copy of Respondent’s brief by mail on March 22, 2018. There are minor, non-substantive differences between the hard copy received by mail on March 22 and the copy received by fax on March 19. For example, the formatting is different between the two copies and Respondent corrected a few misspellings in the hard copy. I will use the faxed copy of Respondent’s Post-Hearing Brief because it was the first copy received and the only variations are typographical in nature.

¹¹ Because statements contained in post-hearing briefs are not evidence, I give no weight to comments made by Respondent in her post-hearing brief that are not supported by evidence in the Administrative Record. See *Surinder Dang, M.D.*, 76 FR at 51,423 n.25.

this day.” ALJ-51, at 2. Respondent explains that closing her medical office triggered a “stressful chain of events,” culminating in eviction from her office and incurring “unforeseen [moving] expenses.” *Id.* After closing her practice, Respondent moved medical equipment, office furniture, and cabinets to her mother-in-law’s garage. *Id.* Respondent also moved “approximately 700 patient charts” to her home in Mission Viejo which doubled as her registered address beginning in September 2013. *Id.* at 2-3. Respondent then began seeing patients at her home. *Id.*

With respect to the controlled substances that were observed unsecured in her home office, Respondent explains that many of them were “expired and waiting to be safely disposed.” ALJ-51, at 5, 14. Additionally, she states that “[n]o patients ever went inside the office,” patients were never left unattended, only one patient was allowed in her home at a time, and she and her husband, S.P., were the only individuals living in the home. *Id.* at 8. Respondent further describes the security in place at her home, explaining that her registered address is located “in a very safe gated community with 24/7 security patrols.” *Id.* at 9. She further argues that her home has a “sophisticated security system” that sounds a “highly audible notification” when doors are opened. *Id.* She also receives email notifications when doors are opened. *Id.* Additionally, Respondent asserts that there is a security camera in her office and in the hallway outside the office. *Id.* Respondent argues that she explained the features of her security system to SA 1 during the April interview. *Id.* at 9, 11. Respondent contends that the security in place at her home was adequate, especially in light of the fact that she intended to relocate her practice to a new office. *Id.* Respondent also claims that she consulted a “pharmaceutical supplier[],” who visited her residence and deemed the security at her home sufficient. *Id.* at 11. Respondent explains that she never obtained a safe because she planned on practicing out of her home temporarily and was “actively negotiating for a new office space.” *Id.*

In regard to the allegation that Respondent failed to maintain adequate inventories, Respondent asserts that she “kept all the medication purchase orders as an inventory guide.”

ALJ-51, at 6. Respondent acknowledges that these purchase orders are not in evidence and contends that she assumed, as a *pro se* litigant, the Government would introduce the documents into evidence. *Id.* at 7.

Respondent also addresses the alleged inconsistencies in her statements to investigators regarding the location of her patient files. She believed some of the missing patient files could have been left in the cabinets or office furniture that were moved into storage after the abrupt closing of her practice. ALJ-51, at 8. She also contends that investigators never requested that she take them to the storage location and further notes that the search warrant authorized investigators to search the storage facility, but they never did. *Id.*

Respondent also discusses the CURES reports that DEA and state investigators ran of her prescribing history. ALJ-51, at 11. Respondent acknowledges that “[Agent] SA 1’s concerns were legitimate”; however, the CURES reports “clearly showed” that Respondent’s patients “did not fit the category for high potential for abuse, addiction or diversion.” *Id.* Respondent does not explain why her patients do not fit this category. *Id.* She also recognizes that urine screening and patient contracts are useful, but argues that such precautions only “need to be implemented” on an individual basis “as determined by medical judgment.” *Id.* at 12. Respondent asserts that reporting to CURES “was not mandatory at first for dispensing physicians.” *Id.* Respondent states that she understands the importance of reporting prescriptions to CURES, and that doing so “helps to provide the best care for our patients and avoid harm.” *Id.*

Respondent provides an explanation regarding the prescription bottles with labels that bore patients’ names that were found in her office during service of the search warrant. She argues that it is not uncommon for “patients [to] leave prescriptions with their doctors” for a variety of reasons. ALJ-51, at 14. Without pointing to a specific example, Respondent claims that a patient may leave a prescription bottle with her for it to be administered in the office, to pick it up at a later date, or for “issues of privacy.” *Id.*

Regarding the discrepancies between the controlled substances inventoried by investigators in March and June, Respondent argues that the missing controlled substances were dispensed and documented in a dispensing log, patient chart, or both. ALJ-51, at 14. Presumably, the dispensing log she refers to is Respondent's Exhibit 1.

Respondent argues that the large amount of cash discovered at her home during the search warrant represented "some savings [she] had put away through the years." ALJ-51, at 15. Respondent also states, as she did to investigators, that she was unaware of the marijuana in the suitcase in her garage.¹² *Id.* The firearms found during the search were obtained lawfully for purposes of self-defense "after violence and threats of violence committed by [her] ex-husband." *Id.* Respondent responds that the idea that the firearms played a role in her medical practice is "absurd and slanderous." *Id.*

Addressing the allegation of self-prescribing, Respondent explains that the prescriptions in Government Exhibit 7 were phoned in by either herself or a staff member calling under her supervision. ALJ-51, at 15. According to Respondent, the dispensing pharmacy, E-Compounding, used "generic prescription forms," instead of the proper order form, and incorrectly wrote Respondent's "name on the prescriptions as if [she] were the patient." *Id.* at 15-16. Respondent contends that the pharmacy "failed to adhere to the standard practice of transferring from a pharmacy to any licensing entity, [such] as a medical doctor, when ordering medications for office stocking, thus mischaracterizing the transactions." *Id.* at 16. Further, Respondent explains the pharmacy "should have used an invoice form and not a prescription when [she] was ordering for office stock." *Id.* In her defense, Respondent argues that "[i]f [the pharmacy] recorded my orders as office use using prescriptions under my name I had no way to know." *Id.* Respondent faults the pharmacy for its "poor record keeping" and notes that the pharmacist was "disciplined for that violation among others." *Id.* Respondent states that she never used E-Compounding Pharmacy after December 2012. *Id.*

¹² Respondent does not explain any of the other marijuana found in other locations of her home.

In response to the issue of prescribing to S.P., Respondent argues that “[t]here are no specific regulations or laws prohibiting physicians from treating family members.” ALJ-51, at 17. She then cites the American Medical Association’s Code of Medical Ethics to support the proposition that physicians may provide medical care to family members in emergencies or “‘isolated settings where there are no other qualified physicians available.’” *Id.* Respondent contends that she has always maintained records for her patients and that she obtained S.P.’s previous medical records before treating him as a patient. *Id.* at 18. She also claims, without citing any evidence of record, that some of S.P.’s records were located during the search warrant. *Id.* She then argues that Dr. Munzing gave an expert opinion based solely on CURES reports. *Id.* at 18-19. In essence, Dr. Munzing “gave an opinion on evidence he was not provided with.” *Id.* at 19. Respondent’s argument seems to rest on the assumption that medical files for S.P. were in fact created and never given to Dr. Munzing for review; however, Respondent fails to explain where those records are located and why she has not produced them either during the investigation or these proceedings. *Id.*

Throughout her brief, Respondent cites to ongoing issues in her personal life. Respondent opines that “circumstances of extreme duress in [her] personal life should have been taken into consideration.” ALJ-51, at 12. She also highlights “harassment and stalking” and threats of violence made by her ex-husband. *Id.* at 3, 10, 15. Respondent assures that even during challenging times, she was “trying hard to get back to normal.” *Id.* Additionally, Respondent asserts that she has never been the subject of a medical malpractice lawsuit or a patient complaint. *Id.* at 4. In conclusion, Respondent argues that the Administrative Record does not establish by a preponderance of the evidence that allowing her to retain her COR is “[in]consistent with the public interest.” *Id.* at 19.

Factors One & Three: The Recommendation of the Appropriate State Licensing Board or Professional Disciplinary Authority, and Conviction Record Under Federal or State Laws Relating to the Manufacture, Distribution, or Dispensing of Controlled Substances

In this case, it is undisputed that Respondent holds a valid and current state license to practice medicine in California. Stip. 3. The record contains no evidence of a recommendation regarding Respondent's medical privileges by a relevant state licensing board or professional disciplinary authority. However, possession of a state license does not entitle a holder of that license to a DEA registration. *Mark De La Lama, P.A.*, 76 FR 20,011, 20,018 (2011). Rather, a state medical board's decision to allow a doctor to practice medicine is not dispositive as to whether the doctor's DEA registration is consistent with the public interest. *Patrick W. Stodola, M.D.*, 74 FR 20,727, 20,730 n.16 (2009).

At the hearing, the Government presented evidence that Respondent is not currently licensed to practice medicine in Florida. Tr. 133. Respondent presented Respondent's Exhibit 2, her expired Florida medical license. *[The Government Prehearing Statement alleged, "Respondent is presently not licensed to practice medicine in Florida." ALJ-9, at 3.*^J I address the lack of Respondent's state authority further below; however, as it relates to Factor One it is noted that there is nothing on the record to indicate that the Florida Medical Board has taken any action on Respondent's medical license.]

DEA precedent establishes that where the record contains no evidence of a recommendation by a state licensing board that absence does not weigh for or against revocation. *See Roni Dreszer, M.D.*, 76 FR 19,434, 19,444 (2011) ("The fact that the record contains no evidence of a recommendation by a state licensing board does not weigh for or against a determination as to whether continuation of the Respondent's DEA certification is consistent

^J The RD found that the issue of Respondent's loss of state authority in Florida was not sufficiently noticed, but the Government had noticed it prior to the hearing in its Prehearing Statement, and the Respondent presented arguments regarding her state authority at the hearing; therefore, I find that based on her own submissions during the proceeding, Respondent had adequate notice that her lack of state authority in Florida was at issue. *See Hatem M. Ataya, M.D.*, 81 FR 8221, 8244 (2016).

with the public interest.”). Accordingly, Factor One does not weigh for or against revocation of Respondent’s California registration in this matter.

As to Factor Three, there is no evidence that Respondent has been convicted of an offense under either federal or California law “relating to the manufacture, distribution, or dispensing of controlled substances.” 21 U.S.C. 823(f)(3). However, there are a number of reasons why even a person who has engaged in criminal misconduct may never have been convicted of an offense or even prosecuted for one. *Dewey C. MacKay, M.D.*, 75 FR 49,956, 49,973 (2010), *pet. for rev. denied*, *MacKay v. DEA*, 664 F.3d 808, 822 (10th Cir. 2011). The DEA has, therefore, held that “the absence of such a conviction is of considerably less consequence in the public interest inquiry” and is therefore not dispositive. *Id.* Accordingly, Factor Three neither weighs for nor against revocation in this case.

Factors Two & Four: The Respondent’s Experience in Dispensing Controlled Substances and Compliance with Applicable State, Federal, or Local Laws Relating to Controlled Substances

Factors Two and Four are often analyzed together. *See, e.g., Fred Samimi, M.D.*, 79 Fed. Reg. 18,698, 18,709 (2014); *John V. Scalera, M.D.*, 78 FR 12,092, 12,098 (2013). Under Factor Two, the DEA analyzes a registrant’s “experience in dispensing . . . controlled substances.” 21 U.S.C. 823(f)(2). Factor Two analysis focuses on an applicant’s acts that are inconsistent with the public interest, rather than on an applicant’s neutral or positive acts and experience. *Randall L. Wolff, M.D.*, 77 FR 5106, 5121 n.25 (2012) (explaining that “every registrant can undoubtedly point to an extensive body of legitimate prescribing over the course of [the registrant’s] professional career”) (quoting *Jayam Krishna-Iyer, M.D.*, 74 FR 459, 463 (2009)). Similarly, under Factor Four, the DEA analyzes an applicant’s compliance with federal and state controlled substance laws. 21 U.S.C. § 823(f)(4). Factor Four analysis focuses on violations of state and federal laws and regulations. *Volkman v. DEA*, 567 F.3d 215, 223-24 (6th Cir. 2009) (citing *Gonzales v. Oregon*, 546 U.S. 243, 272, 274 (2006)); *see Joseph Gaudio, M.D.*, 74 Fed. Reg. 10,083, 10,090-91 (2009).

Here, the Government alleges that revocation of Respondent's COR and denial of her pending application is appropriate under Factors Two and Four (as well as Factor Five) for the following reasons: (1) improper storage; (2) failing to maintain proper inventories and dispensing logs; (3) possession of controlled substances with the names of other individuals on the bottle; (4) improperly prescribing controlled substances "for office use"; (5) prescribing to S.P. without maintaining a medical record for S.P.; and (6) displaying a lack of candor during the investigation. ALJ-1, at 2-4.

THE ALLEGATIONS

Improper Storage

Concerning improper storage of controlled substances, the Government asserts that Respondent was found to be improperly storing controlled substances on March 13, 2014, and again on June 13, 2014, in violation of 21 CFR 1301.75(a) and (b). ALJ-1, at 2, paras. 3, 5. Specifically, the Government claims that on both dates, investigators found a variety of controlled substances located on open shelves, on top of the office copier or desk, and in unlocked glass cabinets in Respondent's office. *Id.* The Government alleges that "[n]one of the controlled substances found at Respondent's registered address were secured in a locked cabinet," as required by 21 CFR 1301.75(b). ALJ-1, at 2, para. 3. In addition, the Government claims that on June 13, 2014, the investigators also found marijuana in Respondent's home. ALJ-1, at 2, para. 5. The Government further asserts that the door to Respondent's office where the controlled substances were observed could not be locked. ALJ-1, at 2, para. 3.

DEA regulations provide that controlled substances "shall be stored in a securely locked, substantially constructed cabinet." 21 CFR 1301.75(a), (b). The regulations do not define the term "substantially constructed cabinet." *Peter F. Kelly, D.P.M.*, 82 FR 28,676, 28,689 (2017). DEA decisions, however, provide some indication that a locked room with adequate security features is sufficient to satisfy the storage requirement of Section 1301.75. *See id.* (finding that the Government failed to meet its burden where controlled substances were left in a locked room

*[dedicated to the storage of controlled substances] with an alarm system). Additionally, as noted in *Kelly*, at least one dictionary supports the interpretation of “cabinet” as a small room. *Id.*

Controlled substances were observed in Respondent’s office on two occasions: during service of the AIW in March 2014 and during execution of the search warrant in June 2014. Between those dates, Respondent’s COR authorized her to possess and prescribe controlled substances in Schedules II-V. GE-1, at 1.

During the inspection in March, investigators found multiple bottles of controlled substances on the desk, on the shelf, and on the printer in Respondent’s office. FF 4. In fact, the investigators found “a great deal of controlled substances” in Schedules III-V. Tr. 22; GE-3, at 1-2. Furthermore, the controlled substances found in Respondent’s office were not secured in any way, and there did not appear to be any place to secure them in her office. FF 5. During the inspection, DEA investigators requested that Respondent purchase some type of safe in which to store the controlled substances and Respondent indicated that one would be purchased that day. FF 8. Following the inspection, SA 1 informed Respondent that controlled substances needed to be locked-up. FF 21.

On June 13, 2014, when DEA investigators returned to Respondent’s office the condition of her office looked the same as it did on March 13, 2014, with controlled substances being found all over the office area. FF 35, 36. There was no safe in Respondent’s office on June 13, 2014. *Id.* A bottle of controlled substances was also found in Respondent’s kitchen. *Id.* During the June 13, 2014 search of Respondent’s home, marijuana was discovered in a suitcase in Respondent’s garage. FF 39. Marijuana was also found in Respondent’s kitchen and bedroom. *Id.* [Omitted language from RD.]*^K

Although the record is clear that controlled substances were not “stored in a securely locked, substantially constructed cabinet,” 21 CFR 1301.75(a) and (b), at the time of the

*^K [See *infra* n.16]

inspection and search, the evidence is less than clear concerning whether the door to Respondent's office could be locked. In response to Government counsel's question about whether she noticed a lock on the office door, FF 8, DI 1 responded, "No." Tr. 39. SA 1 was unsure whether there was a lock on the door, stating "I do not believe there was." Tr. 67. DI 2 testified, however, that "[t]here may have been" a lock on the door, but it was open when investigators entered the home to serve the AIW. Tr. 124. The fact that the door was already open when investigators entered the home, however, could be easily explained by the fact that a separate team of officers made the initial entry into the home to clear the way for investigators. Tr. 20, 110, 122; *see Jack A. Danton, D.O.*, 76 FR 60,900, 60,908 (2011) (noting DI "was not the first to see the [unlocked] closet" alleged to be in violation of storage requirement).

It is also troubling that investigators had two opportunities to photograph the door to the office and did not do so. Investigators took extensive photographic evidence of the office during service of the search warrant and could have easily turned the camera on the door. Furthermore, the fact that three investigators who inspected Respondent's office on two occasions were unable to testify with confidence that the office door could not be locked undermines the Government's allegation that the "investigators could not lock . . . [the] office door." ALJ-1, at 2, para. 3. If there was a lock on the office door, as DI 2 believes there may have been, Tr. 124, the office could have been locked. The question then becomes, if Respondent could lock her office door, would the manner in which she stored her controlled substances in her office be in compliance with 21 CFR 1301.75(b). *Compare Jeffery J. Baker, D.D.S.*, 77 FR 72,387, 72,394, 72405 (2012) (finding violation where controlled substances were routinely left unattended on a counter in an unlocked room)¹³ *with Peter F. Kelly, D.P.M.*, 82 FR 28,676, 28,689 (2017) (finding no violation where controlled substances were left outside safe but in a locked room *[dedicated to the storage of controlled substances]); *see also United States v. Poulin*, 926 F. Supp. 246, 253

¹³ The storage violation in *Becker* "played little or no role in the disciplinary decision" because the respondent introduced evidence that the deficiencies had been corrected. *Becker v. DEA*, 541 Fed. App'x 587, 589 (6th Cir. 2013). That is not the case here.

(D. Mass. 1996) (reasoning that controlled substances kept “in an unlocked area” violated Section 1301.75). I find that it would not.

In a fairly recent case, the Administrator concluded that a registrant was in substantial compliance with 21 CFR 1301.75(b) when he left a small amount of controlled substances outside a safe overnight so they could be administered in the morning, but where the controlled substances were also in a small locked room and the office was protected by a security alarm system. *Kelly*, 82 FR at 28,689. In *Kelly*, however, the controlled substances at issue involved medications that the registrant occasionally left “out overnight for his office manager to administer to patients who were undergoing procedures the following morning.” *Id.* at 28,678. In addition, the decision “noted that the room in which the medications were kept was locked, that only the Respondent and his office manager had a key, that the room had a steel reinforced door and steel doorframe with a deadbolt, that Respondent’s office was protected by a security system, and that there was no evidence that the room ‘was used for any purpose other than to store controlled substances’” *Id.*

Unlike Dr. Kelly, who occasionally set out medications in a room that was only used to store controlled substances so that his office manager could administer the medication to early arriving patients, Respondent had controlled substances continually strewn all about her office. FF 3; *see* GE-5; GE-11, at 7-9. Even though Respondent stated in a sworn interview that “[. .

.]^{*L} her office is protected by an alarm system,¹⁴ the area where she was storing her controlled substances was her actual office, it was not an area set aside for the storage of controlled substances.¹⁵ *[I am omitting a section of the RD and footnote 20 based on relevance and omitting the RD's analysis related to marijuana under Factors 2 and 4.¹⁶

Furthermore, the evidence on the record demonstrates that Respondent was fully on notice that her office did not constitute adequate secure storage under DEA regulations, because she was informed of that fact by both SA 1 and DI 1 on March 13, 2014, and she made no effort to correct this violation by June 13, 2014. FF 20 & 21.]

Accordingly, the allegation contained in Paragraphs 3 and 5 of the OSC that Respondent violated 21 CFR 1301.75(b) on both March 13, 2014, and June 13, 2014, when investigators found a variety of controlled substances located on open shelves, on top of the office copier or

^{*L} [The ALJ found that Respondent had stated during her interview that she always kept her office locked, but I do not find that the record supports this statement. She stated that when she was in her previous office (before she moved her office to her home), the door where she “stored medication, was all the time locked See right now it’s my house, so I’m –I’m only there, uh—uh, with my husband , and I have an alarm system But I had in mind to change the lock.” GE-12, at 78. When SA 1 pointed out that there could be patients that walk by the office unsupervised, Respondent stated, “[y]eah, the door is locked all—I mean closed at all times.” *Id.* at 81. The exhibit supports that if there was a lock on the office door, Respondent was only keeping it closed at all times, not locked, and whatever lock might have been on the door for some reason needed to be changed. Further, although Respondent claimed that for her office, “[e]very time you open the door, there’s a sensor, so it makes a noise and it communicates to my phone,” GE-12, at 79, there was also a large window depicted in the pictures of her office, for which she did not describe any security. GE-5, at 1. Even if I could take the security measures that she described as true, her office does not appear to be similar to a locked room dedicated to the storage of controlled substances, and most importantly, she was specifically told that her security was inadequate and did nothing to remedy it. The record does not support a finding that Respondent’s office could constitute a locked cabinet in order to comply with DEA regulations.]

¹⁴ Because the DEA was not a party to the proceeding in which Respondent gave this sworn statement concerning the security of her office, the weight that can be given to the statement is “substantially diminished.” *Lon F. Alexander, M.D.*, 82 FR 49,704, 49,730 n.54. (2017).

¹⁵ *[omitted. It is noted that there was also evidence that contradicted her off-the-record claims about the level of security of her home in that there was a suitcase of marijuana about which she allegedly had no knowledge in her garage, and she felt the need to have three firearms for protection from her ex-husband.]

¹⁶ In its Post-Hearing Brief, the Government has made no distinction between how Respondent should have been storing the Schedule III-V controlled substances found in her office and the marijuana, none of which was found in her office. ALJ-50, at 18-19. While the OSC specifically addresses Respondent’s failure to properly store controlled substances, “including marijuana,” ALJ-1, at 2, para. 5, with respect to storage the Government’s Post-Hearing Brief focused only upon “the controlled substances that were located in her office.” ALJ-50, at 19. Rather than addressing marijuana as a storage concern, in its Post-Hearing Brief the Government argues, for the first time, that Respondent’s possession of marijuana should be considered under Factor 5. ALJ-50, at 21. *[The RD stated that “[t]he Government also seemingly alleged that [Respondent] violated 21 CFR 1301.75(a) by failing to keep marijuana, a Schedule I controlled substance, ‘in a securely locked, substantially constructed cabinet.’” RD, at 32 (citing ALJ-1, at 2, para. 5). I find that the OSC was unclear as to the legal basis of the allegation related to marijuana; therefore, I am omitting the RD’s analysis under Factors 2 and 4 about whether the storage requirement would apply to the marijuana in Respondent’s home as irrelevant.]

desk, and in unlocked glass cabinets in Respondent's office is **SUSTAINED**. These sustained allegations weigh in favor of revoking Respondent's registration, and denying her pending application. *[Omitted, *see infra* n.16].^{17 18}

Recordkeeping

The Government next alleges that Respondent failed to "maintain complete and accurate records," in violation of Cal. Bus. & Prof. Code § 2266; Cal. Health & Safety Code § 11190; 21 U.S.C. 827(a)(1), and (a)(3); 21 U.S.C. 842(a)(5); 21 CFR 1304.03(b), 1304.04(a), 1306.04, 1304.11(c), 1304.21(a), and 1304.22(c). ALJ-1, at 2, paras. 4-5. Specifically, the Government contends that during the March inspection and June search, investigators were unable to find an initial inventory; biennial inventory; 222 Forms; or dispensing log, for Respondent's controlled substances. *Id.* The Government claims that the only records Respondent provided to investigators "were a series of invoices from on or about May 23, 2013 through March 13, 2014." *Id.* The Government also alleges that the controlled substances inventoried in Respondent's office in June varied from what was counted in March, and that Respondent failed to account for the discrepancies through the production of dispensing records, in violation of 21 CFR 1304.22(c) and 1306.04, and Cal. Health & Safety Code § 11190. ALJ-1, at 3, para. 6.

Inventories

Registrants are required to keep inventories for two years from the date of their creation. *Margy Temponeras, M.D.*, 77 FR 45,675, 45,678 (2012) (citing 21 U.S.C. 827(b)); 21 C.F.R. § 1304.04(a). Respondent changed her registered address on September 26, 2013, to 22391 Sunbrook, Mission Viejo, California, the location that investigators searched in March and June of 2014. *Stip.* 4; *GE-1*, at 4. At the time of executing both the AIW and search warrant, two years had not lapsed from the date that Respondent changed her registered location to her residence in Mission Viejo. Thus, Respondent should have had an initial inventory available for

¹⁷ *[Omitted]

¹⁸ *[Omitted]

inspection if it existed. 21 U.S.C. 827(b); 21 CFR 1304.04(a); *see also* Zvi H. Perper, M.D., 77 FR 64,131, 64,141 (2012) (finding that “Respondent failed to conduct the required initial inventory after moving to a new practice location”).¹⁹

During the March inspection, DI 1 asked Respondent to provide the initial and biennial inventories of controlled substances used at her registered address. FF 14. Respondent did not provide them.²⁰ *Id.* Although DI 1 could not recall if she requested the initial inventory again in June, she testified that Respondent did not provide one at that time. Tr. 39; GE-14. If Respondent had created an initial inventory, it is not in the Administrative Record. In fact, there is no evidence in the record indicating that Respondent ever provided DEA with copies of her initial inventory.

Although there is no direct evidence that Respondent failed to create an initial inventory of the controlled substances she maintained at her Mission Viejo address,²¹ the fact that Respondent did not provide an inventory to the investigators and has not produced one during the course of these proceedings strongly suggests that Respondent never took an initial inventory at that location. *See Odette L. Campbell, M.D.*, 80 FR 41,062, 41,078 (2015) (reasoning that investigator’s inability to find 222 Forms and registrant’s failure to provide them demonstrates non-compliance). Further, inventories must be made “available . . . for inspection and copying” upon request by DEA investigators, which Respondent failed to do when requested by DI 1. 21 U.S.C. 827(b); Tr. 24, 39.

Accordingly, the allegation that Respondent failed to maintain an initial inventory, in violation of 21 U.S.C. 827(b) and 21 CFR 1304.04(a), as alleged in paragraph 4 of the OSC, is **SUSTAINED**. This sustained allegation weighs in favor of revoking Respondent’s registration, and denying her pending application. *[Omitted].

¹⁹ 21 CFR 1304.11(a) requires that “[a] separate inventory shall be made for each registered location”

²⁰ *[Omitted footnote. The ALJ did not sustain the allegation related to the biennial inventory and I agree.]

²¹ The DI testified that she asked Respondent for her initial and biennial inventories, and not whether she ever made an initial inventory in the first place. *See* Tr. 24-25; *Margy Temponeras, M.D.*, 77 FR 45,675, 45,678 (2012) (noting respondent admitted to state inspector that an initial inventory had never been made).

Dispensing Logs

One of a registrant's recordkeeping responsibilities under Federal law includes the requirement to document each instance in which the registrant dispenses a controlled substance to a patient.²² 21 C.F.R. § 1304.22(c). Stated differently, registrants must document dispensing activity²³ by maintaining "complete and accurate" dispensing logs. 21 U.S.C. § 827(a)(3); 21 C.F.R. § 1304.22(c). To be compliant, a dispensing log must include, among other things: "the name of the substance;" "the name and address of the person to whom [the substance] was dispensed;" "the date of dispensing;" and "the number of units or volume dispensed." *Id.* at § 1304.22(a)(2)(i), (c). California law imposes similar requirements on practitioners to document information such as the patient's name, address, and telephone number, as well as certain details about the substance, when the practitioner dispenses controlled substances in Schedules II, III, or IV. Cal. Health & Safety Code § 11190(c)(1).

The record shows that DI 1 asked Respondent for her dispensing logs on March 13, 2014, and Respondent did not provide any. FF 12, 14. Respondent said the dispensing logs were at her mother-in-law's home in Lake Forest, California. FF 14. DI 1 again requested dispensing records at the time of conducting the June search, and again DI 1 testified that Respondent failed to provide investigators with her dispensing logs or tell them where such records were kept.²⁴ FF 38. Likewise, DI 2 testified that investigators asked Respondent in both March and June for her dispensing records and that she never provided any. Tr. 128, 132, 322.

Although DI 1 and DI 2 testified they never received a dispensing log from Respondent, Tr. 24, 35-36, 39, 49-50, 128, 132, the property receipt from the June 2014 search indicates that a

²² The Government's Post-Hearing Brief provides little in the way of argument or analysis on this issue. The Government addresses this allegation in one sentence and without any citations to DEA decisions. ALJ-50, at 18-19.

²³ For purposes of Section 1304.22(c), "dispensing" refers to a situation where the registrant transfers the controlled medication from the registrant's possession directly to the patient. *Margy Temponeras, M.D.*, 77 FR 45,675, 45,676, 456,86 (2012) (describing how registrant purchased controlled substances for her practice location and then dispensed the medication from that location to patients, and discussing the requirements of Section 1304.22).

²⁴ Although being handcuffed during the search may have prevented Respondent from retrieving her dispensing log and handing it over to investigators, Respondent could have told them where to find it. Tr. 110, 312.

“Class III Med log” was seized from Respondent’s office. GE-14, at 9. The Government did not introduce the “Class III Med log” into evidence. At the hearing, however, Respondent produced a 10-page photocopied document that she testified was seized during the search. Tr. 302-03; RE-1. “Class III Meds Dispensing Log” is written on the cover of the exhibit. RE-1, at 1.

Respondent testified that she received copies of the document in 2016 from the district attorney prosecuting her criminal case.²⁵ Tr. 302-03. DI 1 and DI 2 testified that they had never seen the document before. Tr. 318, 322.

Assuming Respondent’s Exhibit 1 is Respondent’s dispensing log, it fails to satisfy her recordkeeping responsibility under Section 1304.22(c) for a number of reasons. First, it fails to explain the variances discovered in Respondent’s office stock between March and June 2014 when investigators counted the controlled substances on-hand in her home office. The DI testified that “[t]here were missing controlled substances” in June compared to the inventory taken in March. Tr. 40-41, 57-58. DI 1 characterized the discrepancy as significant. Tr. 40. DEA precedent establishes that the inability to account for controlled substances missing from a registrant’s inventory by production of dispensing records constitutes a violation of Section 1304.22(c). *Paul Weir Battershell, N.P.*, 76 Fed. Reg. 44,359, 44,366-67 (2011). In other words, a practitioner violates DEA regulations where she is unable to produce dispensing records explaining overages or shortages in the practitioner’s supply of controlled substances. *Id.* at 44,366 n.23. For example, in *Daniel Koller, D.V.M.*, the Administrator found a violation of 21 C.F.R. § 1304.22(c) where respondent failed to provide dispensing records notwithstanding the fact that respondent possessed controlled substances at his home and was dispensing controlled substances from that location. 71 Fed. Reg. 66,975, 66,982 (2006). Such is the case here.

²⁵ I admitted the document into evidence over Government’s objection even though Respondent failed to disclose in her prehearing statements that she intended to introduce the document into evidence. Tr. 303-04. While Respondent offered her inexperience for her failure to disclose the document, the Government knew of the document’s existence. Tr. 305; GE-14, at 9. In fact, the log is identified in the Government’s own exhibit. See GE-14, at 9, and *supra* note 9.

Comparing Respondent's Exhibit 1 to the inventories taken during the March and June searches reveals that Respondent's dispensing log fails to account for several controlled substances. RE-1; GE-3; GE-14, at 11-12; *see Paul Weir Battershell, N.P.*, 76 Fed. Reg. at 44,366 n.23 (finding violation where missing controlled substances could not be accounted for by dispensing records); *Satinder Dang, M.D.*, 76 Fed. Reg. 51,424, 51,429 (2011) (deeming it inconsistent with the public interest where dispensing logs failed to include all instances of dispensing). Here, Respondent's Exhibit 1 fails to explain the discrepancies found in Respondent's stock of the following substances: 360 tablets of alprazolam; 22 tablets of diethylpropion; *[57.5] tablets of hydrocodone 10/325 mg; 60 tablets of hydrocodone 7.5/200 mg; 90 tablets of temazepam; and 90 tablets of zolpidem tartrate.²⁶

To the extent that there are unresolved discrepancies between the controlled substances counted during the March inspection and the June search, the logical conclusion based on the lack of additional dispensing records in evidence is that Respondent failed to maintain the required records. Notwithstanding Respondent's Exhibit 1, the fact that investigators never found other dispensing records that could reconcile the variances between March and June, despite asking multiple times for her dispensing logs, is "persuasive proof of non-compliance." *Odette L. Campbell, M.D.*, 80 Fed. Reg. at 41,078. Where investigators are unable to find dispensing records for certain medications, it is reasonable to infer that such records were never

²⁶ Investigators counted 750 tablets of alprazolam in March and 0 tablets in June, and Respondent's Exhibit 1 indicates 390 tablets were dispensed between those dates, meaning 360 tablets of alprazolam are not accounted for in Respondent's Exhibit 1. GE-3, at 1; GE-14, at 11-12. Investigators counted 106 tablets of diethylpropion in March and 0 tablets in June, and Respondent's Exhibit 1 indicates 84 tablets had been dispensed between those dates, meaning 22 tablets of diethylpropion are not accounted for in Respondent's Exhibit 1. GE-3, at 2; GE-14, at 11-12. Investigators counted *[462] tablets of hydrocodone 10/325 mg in March and 344.5 tablets in June, and Respondent's Exhibit 1 indicates 60 tablets had been dispensed between those dates, meaning *[57.5] tablets of hydrocodone 10/325 mg are not accounted for in Respondent's Exhibit 1. GE-3, at 1; GE-14, at 11. Investigators counted 60 tablets of hydrocodone 7.5/200 mg in March and 0 tablets in June, and Respondent's Exhibit 1 indicates 0 tablets had been dispensed between those dates, meaning 60 tablets of hydrocodone 7.5/200 mg are not accounted for in Respondent's Exhibit 1. GE-3, at 1; GE-14, at 11-12. Investigators counted 263 tablets of temazepam in March and 173 tablets in June, and Respondent's Exhibit 1 indicates 0 tablets had been dispensed between those dates, meaning 90 tablets of temazepam are not accounted for in Respondent's Exhibit 1. GE-3, at 1; GE-14, at 11. Investigators counted 360 tablets of zolpidem tartrate in March and 0 tablets in June, and Respondent's Exhibit 1 indicates 270 tablets had been dispensed between those dates, meaning 90 tablets of zolpidem are not accounted for in Respondent's Exhibit 1. GE-3, at 1; GE-14, at 11-12. *See infra* pp. 41-44.

created. *Id.* Further, whether the discrepancies “are attributable to outright diversion” or simply “the failure to maintain accurate records,” is not relevant. *Ideal Pharmacy Care, Inc., d/b/a Esplanade Pharmacy*, 76 Fed. Reg. 51,415, 51,416 (2011). What matters to the public interest inquiry is the fact that Respondent could not account for a significant number of controlled substances by adequate documentation. *Id.*

Second, Respondent’s Exhibit 1 does not contain patient addresses or phone numbers, as required by 21 C.F.R. § 1304.22(c) and California law. RE-1, at 2-10; Cal. Health & Safety Code § 11190(c)(1); *Satinder Dang, M.D.*, 76 Fed. Reg. at 51,429 (dispensing records lacked patient addresses). Finally, Respondent’s Exhibit 1 does not contain dispensing information going back to the date that Respondent relocated her office to her home, as required by DEA’s inventory regulations. *Paul H. Volkman*, 73 Fed. Reg. 30,630, 30,643-44 (2008) (DEA unable to locate dispensing records for one year); *Edmund Chein, M.D.*, 72 Fed. Reg. 6580, 6593 (2007) (dispensing log covered only seven months); 21 C.F.R. § 1304.04(a). In fact, Respondent’s Exhibit 1 documents about 70 instances of dispensing over a period of 6 months. RE-1, at 2-10. While Respondent indicates in her post-hearing brief that she documented instances of dispensing in patient charts and not a separate dispensing log, ALJ-51, at 14, even if true, that statement cannot be treated as evidence. *See supra* note 11. Additionally, Respondent never provided testimony on this point while under oath²⁷ at the hearing and did not introduce any patient charts demonstrating that she did in fact record the dispensing of controlled substances in patient charts.^{*M} Without any evidence in the record supporting Respondent’s post-hearing contention, the Government’s evidence on this allegation stands unrebutted.

²⁷ Although Respondent did not offer this argument in her sworn testimony at the hearing, she did explain to SA 1 in the April interview, which was under oath, that she documented dispensing of controlled substances in patient charts. GE-12, at 69. I cannot consider Respondent’s statement as evidence, however, because it was not made at the DEA’s hearing. *See Lon F. Alexander, M.D.*, 82 FR 49,704, 49,730 n.56 (2017) (“[A] respondent is required to present his evidence in the Agency’s proceeding.”).

^{*M} [I agree with the ALJ and find that his analysis here addresses the same argument that Respondent made in her Exceptions. Resp Exceptions, at 19.]

Failure to provide DEA with accurate records which correctly reflect the controlled substances dispensed by a registrant constitutes a recordkeeping violation and is *[evidence that Respondent's registration is] inconsistent with the public interest. *The Medicine Shoppe*, 79 FR 59,504, 59,516 (2014) (citing *Jack A. Danton, D.O.*, 76 FR 60,900, 60,919 (2011)). In light of the foregoing, the allegation that Respondent failed to maintain "complete and accurate" dispensing records, as set forth in paragraph 4 of the OSC, in violation of 21 U.S.C. 827(a)(3), 21 CFR 1304.22(c), and Cal. Health & Safety Code § 11190, is **SUSTAINED**. This sustained allegation weighs in favor of revoking Respondent's registration and denying her pending application.

Receiving Records

The Government's next recordkeeping allegation concerns receiving records. ALJ-1, at 2, para. 4. Specifically, the Government contends that Respondent was unable to provide any receiving records, such as DEA 222 Forms, to investigators in March and June 2014, other than a series of invoices, in violation of 21 U.S.C. 827 and 842(a)(5), and 21 CFR 1304.21(a). ALJ-1, at 2, para. 4.

During the inspection in March 2014, DI 1 requested recordkeeping documents from Respondent, specifically invoices. FF 17. The invoices that Respondent provided are contained in Government Exhibit 2. *Id.* Those invoices show that between May 23, 2013, and March 7, 2014, Respondent received the following controlled substances:

Controlled Substance	Total Quantity Received	Reference
Hydrocodone 10/325 mg	300 tablets	GE-2, at 1-3
Phentermine 37.5 mg	2,520 tablets	GE-2, at 1-3; 4, 6-7; 5
Furosemide 20 mg	2,000 tablets	GE-2, at 8-9
Testosterone 100 mg/ml 10 ml	3 vials	GE-2, at 11
Testosterone Propionate	4 vials	GE-2, at 11

100 mg/ml 10 ml		
Stanozolol 50 mg/ml 10 ml	3 vials	GE-2, at 11
Tri-Testosterone 200/50/200 mg/ml 10 ml	6 vials	GE-2, at 11
Anastrozole 1 mg	1,350 tablets	GE-2, at 12-18
Fluoxetine 20 mg	300 tablets	GE-2, at 12-14
Clonidine .1 mg	600 tablets	GE-2, at 15, 17-18

On March 13, 2014, however, Respondent possessed quantities of 11 different controlled substances for which she had no invoices, and she also possessed 462 tablets of hydrocodone. *Compare* GE-3, at 1-2, *with* the above table. Based on the controlled substances that were counted in the office during the inspection, Respondent should have had more invoices than the 9 invoices she provided.²⁸ FF 18.

While the Government also alleged that Respondent did not produce any DEA 222 Forms, none of the investigators provided any testimony regarding 222 Forms. Based on the testimony of all four investigators, it is not possible to discern whether they were looking for 222 Forms, whether Respondent should have kept 222 Forms, or whether they asked for receiving records other than invoices. Furthermore, Respondent did not possess any Schedule I or II controlled substances on March 13, 2014. *See* GE-3, at 1-2. Since DEA 222 Forms are only used to order Schedule I and II controlled substances, there is no evidence before me suggesting that Respondent was missing any DEA 222 Forms. *See* 21 CFR 1305.03.

Accordingly, the allegation that Respondent failed to maintain receiving records, as alleged in paragraph 4 of the OSC, in violation of 21 CFR 1304.21(a), is **SUSTAINED**. This sustained allegation weighs in favor of revoking Respondent's registration, and denying her pending application. The allegation that Respondent failed to maintain DEA 222 Forms,

²⁸ Government Exhibit 2 consists of 18 invoices, but several of the invoices are duplicates.

however, as alleged in paragraph 4 of the OSC, is **NOT SUSTAINED**, because Respondent did not possess any Schedule I or II controlled substances on March 13, 2014.

Variance

The Government also alleged that when Respondent's controlled substances were inventoried on June 13, 2014, she was unable to account for some of the controlled substances that she possessed on March 13, 2014. ALJ-1, at 3, para. 6. Specifically, the Government alleges that Respondent was not able to account for:

25 bottles of Alprazolam 1 mg, containing 30 tablets (750 tablets)

10 bottles of Clonazepam 1 mg, containing 30 tablets (300 tablets)

3 bottles of Diethylpropion HCl 25 mg, containing 28 tablets (84 tablets)

3 bottles of Hydrocodone 10/325 mg, containing 30 tablets (90 tablets)

2 bottles of Hydrocodone/IBU 7.5/200 mg, containing 30 tablets (60 tablets)

64 bottles of Phentermine 37.5 mg, containing 30 tablets (1,920 tablets)

3 bottles of Temazepam 30 mg, containing 30 tablets (90 tablets)

12 bottles of Zolpidem 10 mg, containing 30 tablets (360 tablets)

10 vials of various anabolic steroid and testosterone-related products

Id. The Government did not allege that Respondent's inability to account for these controlled substances was an independent violation of law or regulations, but asserted that she was unable to account for the controlled substances because she did not have any dispensing logs. *Id.* In support of this allegation the Government cited to 21 CFR 1304.22(c), 21 CFR 1306.04, and Cal. Health and Safety Code § 11190. *Id.*

It is the Government's responsibility to "sift through the records and highlight that information which is probative of the issues in the proceeding." *Top RX Pharmacy*, 78 FR 26,069, 26,069-70 n.7 (2013) (quoting *Gregg & Son Distribs.*, 74 FR 17517, 17517-18 n.1 (2009)); see also *James William Eisenberg, M.D.*, 77 FR 45,663, 45,674 n.47 (2012). To prove the variance, the Government introduced Government Exhibits 3 and 14. In addition, the

Government presented testimony that in comparing the quantity of controlled substances that Respondent had in her office on March 13, 2014, to those found in her office on June 13, 2014, that there was “[a] fair amount” fewer controlled substances in Respondent’s office in June. Tr. 131-32; *see also* ALJ-50, at 7, para. 26. The Government, however, has made absolutely no effort to explain how it determined the variances it alleged in paragraph 6 of the OSC.

The following table lists the specific controlled substances the Government alleged that Respondent could not account for on June 13, 2014. The table compares the inventory of those controlled substances taken by the DEA on March 13, 2014, with the inventory taken on June 13, 2014 from Respondent’s office. In addition, the table includes the number of these controlled substances that Respondent dispensed between those two dates, as indicated by her dispensing log that was seized during the search on June 13, 2014.

Controlled Substance	AIW on March 13, 2014	Search Warrant on June 13, 2014	Dispensed²⁹	Reference
Alprazolam 1 mg	750 tablets	0 tablets	390 tablets	GE-3, at 1; GE-14, at 11-12; RE-1, at 5-9
Clonazepam 1 mg	300 tablets	300 tablets	0 tablets	GE-3, at 1; GE-14, at 11
Diethylpropion 25 mg	106 tablets	0 tablets	84 tablets	GE-3, at 2; GE-14, at 11-12; RE-1, at 5

²⁹ This column reflects controlled substances reportedly dispensed by Respondent between March 13, 2014, and June 13, 2014, as reported in Respondent’s Exhibit 1. There is no evidence that the Respondent received any new controlled substances between March 13, 2014 and June 13, 2014.

Hydrocodone 10/325 mg	462 tablets* ^N	344.5 tablets	60 tablets	GE-3, at 1; GE-14, at 11; RE-1, at 6
Hydrocodone 7.5/200 mg	60 tablets	0 tablets	0 tablets	GE-3, at 1; GE-14, at 11-12
Phentermine 37.5 mg	616 tablets	187 tablets	660 tablets	GE-3, at 2; GE-14, at 11; RE-1, at 5-9
Temazepam 30 mg	263 tablets	173 tablets	0 tablets	GE-3, at 2; GE-14, at 11-12
Zolpidem 10 mg	360 tablets	0 tablets	270 tablets	GE-3, at 2; GE-14, at 11-12; RE-1, at 6-9

While this table reveals that Respondent could not account for some of the controlled substances she was missing on June 13, 2014, the numbers are not as large as those alleged by the Government. For example, Respondent was not missing any clonazepam, and she actually accounted for more phentermine on June 13, 2014, than she started with on March 13, 2014.³⁰ In

^{*N} The ALJ noted 810 tablets, but upon review, I counted 15 bottles of 30 count and 12 tablets as 462 tablets.

³⁰ Although the Government alleged that Respondent possessed 1,920 tablets of phentermine on March 13, 2014, ALJ-1, at 3, para. 6, the inventory that was conducted that day only shows she had 616 tablets that day. GE-3, at 1. The Government offered no evidence to support the allegation that on March 13, 2014, Respondent possessed 64 bottles of phentermine, each containing 30 tablets. Further, as the below table illustrates, Respondent had other controlled substances where she had more of those substances on June 13, 2014, than she did on March 13, 2014. These overages also cannot be explained by evidence in the Administrative Record.

Controlled Substance	AIW on March 3, 2014	Search Warrant on June 13, 2014	Reference
Hydrocodone 7.5/500 mg	120 tablets	150 tablets	GE-3, at 1; GE-14, at 11
Temazepam 15 mg	0 tablets	115 tablets	GE-3, at 1-2; GE-14, at 11

addition, while the Government alleged that Respondent could not account for “10 vials of various anabolic steroid and testosterone-related products,” ALJ-1, at 3, para. 6, the March 13, 2014 inventory lists no such products. GE-3, at 1-2. Nevertheless, despite the Government’s failure to explain where it came up with some of the quantities of controlled substances in paragraph 6 of the OSC that it alleged Respondent could not account for, the direct comparison detailed in the above table demonstrates that on June 13, 2014, Respondent was not able to account for “[a] fair amount” of the controlled substances she possessed on March 13, 2014. Tr. 131.

None of the regulations cited by the Government in the OSC, 21 CFR 1304.22(c), 21 CFR 1306.04, and Cal. Health and Safety Code § 11190, require that Respondent be able to account for her controlled substances. Both 21 CFR 1304.22(c) and Cal. Health and Safety Code § 11190 address the requirement to maintain dispensing logs. The other cited regulation, 21 CFR 1306.04, addresses the requirements for issuing prescriptions and has no relevance to Respondent’s inability to account for her controlled substances. The inability to account for a significant number of dosage units, however, creates a grave risk of diversion. *The Medicine Shoppe*, 79 FR 59,504, 59,516 (2014) (citing *Medicine Shoppe-Jonesborough*, 73 FR 364, 367 (2008) (finding 50 dosage units a significant amount)). In this case, because Respondent was unable to account for more than 50 dosage units of several controlled substances, I find that she was unable to account for a significant amount of controlled substances.

[*Omitted. The violations of law have been considered with regard to her lack of complete dispensing logs.]*^o

Illegal Prescribing to Self and to S.P.

APAP Codeine 300/30 mg	266 tablets	295 tablets	GE-3, at 1; GE-14, at 11
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^o[The RD also noted that the OSC had alleged violations of 21 CFR 1306.04 and Cal. Health & Safety Code § 11350 based on Respondent’s possession of prescription pill bottles belonging to at least five other individuals, L.F., B.S., D.V., J.W., and D.D. RD, at 44-45 (citing ALJ-1, at 3, para. 7). I am omitting this section, but I agree with the RD that there is not substantial evidence on the record to support these allegations. *Id.*]

The Government next alleged that Respondent unlawfully issued over 75 prescriptions between February 16, 2010, and July 13, 2015.³¹ ALJ-1, at 3, para. 8. The Government alleges that the prescriptions for controlled substances that Respondent issued to herself and to her husband, S.P., during this period were issued for “other than a legitimate medical purpose or outside the usual course of professional practice.” *Id.*

Under the Controlled Substances Act (“CSA”), it is unlawful for a person to distribute controlled substances, except as authorized under the CSA. 21 U.S.C. 841(a)(1). To combat abuse and diversion of controlled substances, “Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA.” *Gonzales v. Raich*, 545 U.S. 1, 13 (2005). To maintain this closed regulatory system, controlled substances may only be prescribed if a DEA registrant writes a valid prescription. *Carlos Gonzalez, M.D.*, 76 FR 63,118, 63,141 (2011). As the Supreme Court explained, “the prescription requirement . . . ensures that patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, [it] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.” *Gonzales v. Oregon*, 546 U.S. at 274 (2006) (citing *United States v. Moore*, 423 U.S. 122, 135, 143 (1975)).

A controlled substance prescription is not valid unless it is “issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” 21 CFR 1306.04(a). Federal regulations further provide that “[a]n order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of [21 U.S.C. 829] and . . . the person issuing it[] shall be subject to the penalties provided for violations of [controlled substance laws].” *Id.*; see 21 U.S.C.

³¹ The Government did not address any prescription written on July 13, 2015. The most recent prescription the Government identified during the hearing was written by Respondent to her husband, S.P., on September 16, 2014. GE-8, at 27.

842(a)(1) (establishing that, under the CSA, it is illegal for a person to distribute or dispense controlled substances without a prescription, as is required under 21 U.S.C. 829).

There are four ways to prove that a practitioner violated the prescription requirements of 21 CFR 1306.04(a): (1) by providing expert testimony that the prescription was not issued for a legitimate medical purpose or in the usual course of professional practice; (2) by showing that a practitioner violated “a state medical practice standard which is sufficiently tied to a state law finding of illegitimacy to support a similar finding under Federal law”; (3) by demonstrating that the respondent “knowingly diverted drugs”; and/or (4) by showing that the respondent violated a state medical practice standard “which has a substantial relationship to the CSA’s purpose of preventing substance abuse and diversion.” *Jack A. Danton, D.O.*, 76 FR 60,900, 60,901 (2011); *see also Joe W. Morgan, D.O.*, 78 FR 61,961, 61,978 (2013).

In this case, the Government has presented evidence that touches on two of the four methods of proving a violation of 21 CFR 1306.04(a). First, the Government presented the expert testimony of Dr. Munzing that the prescriptions that Respondent issued to both herself and S.P. were not issued for a legitimate medical purpose and that they were also issued outside the usual course of professional practice. FF 55-62, 64-67. Second, the Government’s evidence suggests that by failing to properly keep records of the controlled substances Respondent stored in her office and the manner in which she prescribed controlled substances, she violated state standards which have a substantial relationship to the CSA’s goal of preventing diversion. *See* Cal. Health & Safety Code §§ 11153(a), 11170, and 11190.

California Law

California law echoes federal standards and provides that “[a] prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice.” Cal. Health & Safety Code § 11153(a). State law further adds that prescribing a controlled substance without first conducting a proper medical examination “constitutes unprofessional conduct.” Cal. Bus. &

Prof. Code § 2242(a). California law prohibits a practitioner from prescribing “a controlled substance for himself.” Cal. Health & Safety Code § 11170.

California’s controlled substance laws set forth several requirements related to the documentation and reporting of prescriptions. Specifically, California practitioners must document certain information when they prescribe or administer a controlled substance, depending on the schedule of the drug. Cal. Health & Safety Code § 11190. Additionally, failing “to maintain adequate and accurate records relating to the provision of services to [] patients constitutes unprofessional conduct.” *Id.* at § 2266. *[Omitted.]

Self-Prescribing

The Government alleged that between February 16, 2010, and November 29, 2012, Respondent issued at least 40 prescriptions to herself for controlled substances “for office use,” in violation of 21 CFR 1306.04(a) and (b), and Cal. Health & Safety Code § 11170. ALJ-1, at 3, para. 8(a). It is further alleged that the prescriptions Respondent wrote “for office use” were without a legitimate medical purpose and were written outside the course of professional practice. *Id.*

DEA regulations prohibit a practitioner from obtaining controlled substances “for the purpose of general dispensing to patients.” 21 CFR 1306.04(b). This makes sense in light of the requirement that for a prescription to be valid, it must be written for a “medical purpose” in the ordinary course of professional practice. *Id.* at § 1306.04(a). [*Omitted]. Relatedly, under California law, “[n]o person shall prescribe, administer, or furnish a controlled substance for himself.” Cal. Health & Safety Code § 11170; Tr. 134, 200. As for the standard of care, Dr. Munzing explained that if a practitioner intends to obtain controlled substances for office use, simply writing “for office use” on the prescription is not the proper procedure in California.³² Tr. 200-01. Dr. Munzing also testified that the American Medical Association’s

³² The Administrative Record contains no evidence explaining the proper procedure a practitioner must use to obtain controlled substances for office use.

Code of Ethics forbids a practitioner from prescribing controlled substances to herself. *Id.* at 200.

Government Exhibit 7 contains 168 prescriptions³³ authorized by Respondent between February 16, 2010, and November 29, 2012, that were either written for herself or for office use instead of a particular patient. FF 61-62, 65-67; GE-7, at 4, 177. The Government further alleged that the prescriptions Respondent issued to herself violated DEA's prescription requirement because they lacked a legitimate medical purpose and were issued outside the course of professional practice. ALJ-1, at 3, para. 8(a) (citing 21 CFR 1306.04(a)). A prescription violates Section 1306.04(a) if it lacks a legitimate medical purpose or was issued outside the course of professional practice in the practitioner's state. *United States v. Nelson*, 383 F.3d 1227, 1233 (10th Cir. 2004). At the very least, testimony and documentary evidence demonstrate that the prescriptions in Government Exhibit 7 were not issued in the course of professional practice. For example, in addressing these prescriptions Dr. Munzing testified that it is outside the standard of care and the course of professional practice in California for a prescription to list "office use" instead of the patient's name. Tr. 201.

At the hearing, the Government directed Dr. Munzing's attention to several prescriptions in Government Exhibit 7 that appear to be examples of prohibited self-prescribing. Dr. Munzing opined that these prescriptions were issued outside the California standard of care. FF 62. As Dr. Munzing noted at the hearing, these prescriptions do not contain any indication they were intended for office use, and instead represent instances of Respondent prescribing a controlled drug to herself, in violation of California law and the California standard of care. FF 57; Tr. 206-10; Cal. Health & Safety Code § 11170. [*Omitted.]

³³ In its Post-Hearing Brief, the Government asserts that Respondent wrote 179 prescriptions to herself, but makes no effort to explain how it came up with that number, except citing to Government Exhibit 7. ALJ-50, at 8, 17. During the hearing, the Government only addressed 168 such prescriptions. I have identified each of those prescriptions in my Findings of Fact. See FF 61-62, 65-67; GE-7, at 4, 177.

Several of the prescriptions were also issued outside the standard of care in California to the extent that they prescribed an extremely high number of pills. FF 59-60. Three prescriptions authorized by Respondent for herself were written for 300, 450, and 600 tablets of phentermine, respectively. FF 59. Phentermine is a Schedule IV controlled substance. Stip. 11. Dr. Munzing testified that 600 tablets of phentermine is “an incredibly high number.” Tr. 213. Further, he added that 450 pills of phentermine are excessive, and a prescription for 450 phentermine tablets would be outside the standard of care in California. Tr. 247-48.

It is also significant that, according to Dr. Munzing, four of the prescriptions Respondent issued to herself contained dosing instructions. FF 63. Because dosing instructions are typically tailored to the patient’s needs at the time of seeing the patient, as opposed to when the substance is obtained, the fact that these four prescriptions are accompanied with specific dosing directions strongly suggests that the prescribed substances were intended to be used by the named patient (i.e., Respondent) and not used as office stock from which to supply other patients. Tr. 226-27.

Thus, Dr. Munzing’s assessment of the prescriptions in Government Exhibit 7 demonstrate that Respondent issued numerous prescriptions outside the course of professional practice in California by prescribing controlled substances to herself, and in a few instances, by prescribing an “incredibly high number” of tablets to herself. *Id.* at 213. In evaluating these prescriptions, Dr. Munzing referred repeatedly to the standard of care in California and based his expert opinion on the assessment that these prescriptions were not issued in the course of professional practice. Essentially, Dr. Munzing’s testimony regarding Government Exhibit 7 overlooked the second aspect of the prescription requirement, namely that a prescription must be issued for legitimate medical treatment to be valid. The fact that Dr. Munzing’s testimony focused almost exclusively on only one end of the equation, however, is inconsequential. *See Wesley Pope, M.D.*, 82 FR 14,944, 14,967 n.38 (2017) (explaining “there is no material difference between” the dual criteria of Section 1306.04(a)). Prescribing a controlled substance

outside the course of professional practice is enough to violate DEA's prescription requirement.

Id.

Further, Respondent's post-hearing attempt to blame the pharmacy for incorrectly filling the "office use" prescriptions cannot be considered as evidence. *See supra* note 9; ALJ-51, at 15-16.*P

Accordingly, the allegation that Respondent issued at least 40 prescriptions to herself for controlled substances between February 16, 2010, and November 29, 2012, outside the course of professional practice and without a legitimate medical purpose, as alleged in paragraph 8(a) of the OSC, and in violation of 21 CFR 1306.04(a) and (b), and Cal. Health & Safety Code § 11170, is **SUSTAINED**. This sustained allegation weighs in favor of revoking Respondent's registration and denying her pending application.

Prescribing to S.P.

The Government also alleged that between April 21, 2012, through June 12, 2014,³⁴ Respondent issued at least 35 prescriptions³⁵ to S.P. outside the course of professional practice or for other than a legitimate medical purpose, in violation of 21 CFR 1306.04(a), Cal. Bus. & Prof. Code § 2242(a), and Cal. Health & Safety Code § 11153(a). ALJ-1, at 3-4, para. 8(b). Specifically, the Government alleged that Respondent issued the prescriptions to S.P. without

*P [Respondent argues that the prescriptions to herself were the fault of E-Compounding Pharmacy's record systems and that the pharmacy "should have used an invoice and not a prescription number when billing [her] orders." Resp Exceptions, at 25. Regardless of whether the pharmacy also erred in filling these prescriptions in this manner, Respondent cannot pass all of the blame on the pharmacy and expect that she absolves herself of responsibility. I do not find her argument credible that she would have no way of knowing that the pharmacy was recording her prescriptions this way. ALJ-51, at 15. The evidence contains several fax cover sheets from her office, "Beauty Mark Wellness Center," listing prescription orders and indicating "Office Use." *See e.g.*, GE-7, at 146, 150, 152, 160, 166, 171, 173, 175, 177, 178. Further, the evidence also includes a prescription signed by Respondent from her prescription pad indicating, "Office Use." GE-7, at 164. Therefore, the evidence on the record does not support Respondent's contention that the blame for the manner in which these prescriptions were recorded and filled lies with the pharmacy and not on her, and I agree with the ALJ's findings regarding these prescriptions.]

³⁴ The Government has not identified which prescriptions match these dates. Of the prescriptions identified by the Government at the hearing, the earliest prescription was written on March 30, 2012, and the most recent was written on September 16, 2014. GE-8, at 27, 67.

³⁵ In its Post-Hearing Brief, the Government asserts that Respondent wrote "approximately 50 prescriptions for controlled substances" to S.P., ALJ-50, at 9, 16, but makes no effort to explain how it came up with that number, except citing to Government Exhibit 8. *See supra* note 6.

conducting a medical examination or documenting a medical examination in S.P.'s patient record.³⁶ ALJ-1, at 4, para. 8(b).

Title 21 CFR 1306.04(a) details the requirements for issuing a valid prescription. That section states that for a prescription to be effective it “must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of [her] professional practice.” 21 CFR 1306.04(a). That section further provides that “[a]n order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of [the Controlled Substances Act].” *Id.* The Cal. Health & Safety Code § 11153(a) closely parallels the language contained in 21 CFR 1306.04(a). Furthermore, the Cal. Health & Safety Code § 2242(a) provides that “[p]rescribing, dispensing, or furnishing dangerous drugs . . . without an appropriate prior examination and a medical indication, constitutes unprofessional conduct.”

Dr. Munzing testified that under the standard of care in California, a practitioner must maintain a medical record for a patient to whom controlled substances are prescribed. FF 51-53; Tr. 180. Specifically, to meet the California standard of care, the patient’s medical record must contain: details of the medical exam, such as medical history, informed consent, diagnosis, and management plan; results of laboratory testing or imaging; PMP reports; and results of drug tests. FF 54. Notes pertaining to the medical examination itself would likely comprise the bulk of the patient’s file, and would narrate details of the patient-physician encounter, including: current complaint; review of symptoms; cause of the complaint; patient’s history of drug and alcohol use; physical examination; and risk and benefits of treatment options. Tr. 176-80.

In this case, the DEA investigators asked Respondent for patient charts when they first went to her home on March 13, 2014. FF 10. While Respondent did have some patient charts in

³⁶ The OSC also alleged that California regulations “explicitly provide that the failure to . . . document . . . an evaluation in a patient’s record, means that the physician is not prescribing in the usual course of professional practice.” ALJ-1, at 4, para. 8. Neither the OSC nor the Government’s Post-Hearing Brief identify any California regulation that supports this allegation. ALJ-1, at 4; ALJ-50, at 16. Rather, the Government’s Post-Hearing Brief focuses on Respondent’s failure to produce the medical record for S.P. ALJ-50, at 16.

her home, she did not have all of the charts that DEA wanted. FF 11-13. Then again on June 13, 2014, investigators were in Respondent's home looking for specific patient charts, to include a chart for Respondent's husband, S.P. FF 44; Tr. 107. The chart for S.P. was not located during either the AIW or the execution of the search warrant. FF 13, 44. Further, S.P.'s patient file is not part of the Administrative Record. As with the initial inventory, the fact that Respondent did not provide S.P.'s medical file when requested to do so by the investigators and has not produced it during the course of these proceedings strongly suggests that Respondent never created a medical file for her husband. *See Odette L. Campbell, M.D.*, 80 FR 41,062, 41,078 (2015) (reasoning that investigator's inability to find 222 Forms and registrant's failure to provide them demonstrates non-compliance).

Here, the Administrative Record demonstrates that between April 21, 2012, and June 12, 2014, Respondent wrote at least 27 prescriptions for controlled substances for S.P. FF 55; GE-8, at 27. Unfortunately, there is no medical record documenting that Respondent performed "an appropriate prior examination" and formulated "a medical indication" concerning S.P. before issuing him prescriptions for controlled substances. *See Cal. Health & Safety Code § 2242(a)*. By issuing those 27 prescriptions to S.P., without documenting the required medical examination, Respondent engaged in "unprofessional conduct." *Id.* Further, because there is no medical record for S.P., the 27 prescriptions that Respondent issued to S.P. for controlled substances were issued outside the standard of care in California. FF 55.

Accordingly, that portion of the Government's allegation that Respondent wrote 27 prescriptions for controlled substances to S.P. outside the course of professional practice and for other than a legitimate medical purpose, as alleged in paragraph 8(b) of the OSC, in violation of 21 CFR 1306.04(a), Cal. Bus. & Prof. Code § 2242(a), and Cal. Health & Safety Code § 11153(a) is **SUSTAINED**. This sustained allegation weighs in favor of revoking Respondent's registration and denying her pending application. [*Omitted.]

***[Lack of Candor**

The Government alleged that the Respondent's lack of candor during the investigation should be considered under Factor Five to provide further weight that Respondent's continued registration is not in the public interest. ALJ-1, at 4, para. 9. The ALJ considered this evidence accordingly under Factor Five, and although I agree with both the ALJ and the Government that in prior DEA decisions,^{*Q} I have often weighed lack of candor under Factor Five, I find it appropriate in this case, given the nature of Respondent's lack of candor, to consider this under my sanctions analysis. I am retaining the ALJ's analysis of the allegation regarding lack of candor and will consider it more thoroughly in the Sanctions below.]

Here, the Government alleged that Respondent displayed a lack of candor during DEA's investigation. ALJ-1, at 4, para. 9. Specifically, the Government alleged that in March 2014 Respondent told DEA investigators that patient files they requested "were not there," and that at least some of the missing files were at a location in Lake Forest, California, for which she did not know the address. *Id.* The Government also alleged that during subsequent questioning, Respondent again stated that the charts requested by the DEA were at another location, and that the dispensing log that DEA requested were with the missing charts, but she did not know the location. *Id.* Finally, the Government alleged that in June 2014, Respondent told a Medical Board investigator that she did not know who owned the marijuana that was found in a suitcase in the garage of her registered location, despite the fact that additional stashes of marijuana and large amounts of cash were discovered throughout her registered location and she and her

^{*Q} [The RD stated that "[t]he DEA has consistently held that "[c]andor during DEA investigations, regardless of the severity of the violations alleged, is considered by the DEA to be an important factor when assessing whether a physician's registration is consistent with the public interest." *Hassman*, 75 FR at 8236 (internal citations and quotations omitted); *see also Hoxie*, 419 F.3d at 483. For example, the DEA held that a respondent's lack of candor weighed against his registration under Factor Five when he lied to DEA investigators "when first confronted" about his wrongful conduct. *Scalera*, 78 Fed. Reg. at 12,100. The DEA "places great weight on a registrant's candor, both during an investigation and in any subsequent proceeding." *Robert F. Hunt, D.O.*, 75 FR 49,995, 50,004 (2010) (citing *The Lawsons, Inc.*, 72 FR 74334, 74338 (2007)). Thus, the DEA may consider a respondent's lack of candor to be a threat to public health and safety. *Annicol Marrocco, M.D.*, 80 FR 28,695, 28,705 (2015)." RD, at 52.]

husband were the only individuals who lived there. *Id.*³⁷

As with any allegation, the Government bears the burden of proof regarding its claim that Respondent “displayed a lack of candor during DEA’s investigation.” ALJ-1, at 4, para. 9.

Concerning this allegation, the Government primarily focuses on statements that Respondent made to investigators while they were at her home on both March 13, 2014, and June 13, 2014. FF 10, 12, 14, 27, 38, 43, 45.

When DEA investigators were at Respondent’s home on March 13, 2014, they asked her for some patient charts. FF 10. While Respondent apparently provided some patient charts, which were in her garage, FF 11, she also told the DEA investigators that other requested patient records were at a storage facility in Lake Forest, California, but she did not know the address of the facility or where it was located. FF 12. Respondent had similar conversations with the DEA investigators concerning her dispensing logs. FF 14. She informed the investigators that her dispensing logs were with the patient records in a storage facility. *Id.* Apparently, these statements were not true.

In a subsequent interview conducted by Special Agent SA 1, Respondent told her that all of the patient charts were located in Respondent’s garage. FF 27. Subsequently, on June 13, 2014, Respondent’s dispensing log, what there was of it, was found and seized from Respondent’s office. GE-14, at 9; RE-1.^{*R} During that search, Respondent also told the investigators that her husband’s medical chart was located in pieces around her house, but the

³⁷ *[Omitted. I find it unnecessary to consider the marijuana, firearms and cash under Factor Five in this case.].

^{*R} [Respondent notes that “all three agents testified that they never seized the dispensing log of Ex. 1, when in fact they did.” Resp Exceptions, at 20. She implies that the facts demonstrate lack of candor on the Government’s behalf, rather than her own. I disagree. It is clear that the reason that the Government did not possess the dispensing log was not adequately explained in the record; however, I agree with the ALJ that the testimony that the Government witnesses presented was credible that they had not seen the log prior to the hearing. I have fully considered the dispensing log in Respondent’s favor. Regarding Respondent’s candor, there is un rebutted testimony that Respondent made a variety of inconsistent statements about the whereabouts of her records, and when Respondent was testifying on cross examination, she avoided questions regarding the dispensing log before ultimately saying that she did not recall whether or not she provided the dispensing log to the investigators. Tr. 309-12. Also, there is no dispute that no dispensing log was provided to or located by the investigators in March, when the dates on the dispensing log suggest that it existed during the AIW. Ultimately, I am not considering Respondent’s lack of candor under the public interest analysis, but I am considering her lack of cooperation with the investigation and inconsistent statements in my decision regarding whether she can be entrusted with a DEA registration below.]

file was never found. FF 45. In addition, during the search on June 13, 2014, a significant amount of marijuana was found in Respondent's home, though none was found in her office. FF 40-41; GE-14, at 4, 14. Despite the quantity of marijuana that was seized and the fact that marijuana was found in the kitchen and bedroom of Respondent's home, as well as in the garage, she claimed she had no knowledge of how it came to be in her home. FF 43. All of this evidence is unrebutted.

The Administrative Record established by a preponderance of the evidence that Respondent was not truthful in her dealings with DEA investigators when they were at her home on March 13, 2014, and again on June 13, 2014. When questioned about missing patient charts and dispensing records, Respondent initially stated that the charts and records were not at her registered location, but rather were at another location. She also professed no knowledge of where that location was. Later, it was determined that the location was the home of her mother-in-law, a location she surely knew. Eventually, her dispensing log was found in her office, rather than at the home of her mother-in-law. When questioned about the marijuana found in her home, Respondent claimed she had no idea where it came from. As stated earlier, given the quantity and the locations of where the marijuana was found in Respondent's home, her claimed lack of knowledge strains credulity.

Accordingly, the Government's allegation, contained in paragraph 9 of the OSC, that Respondent displayed a lack of candor during the DEA investigation is **SUSTAINED**.

*[Omitted. As previously stated, I am considering Respondent's lack of candor under the Sanction section below.]

***[Lack of State Authority in Florida]**

According to Florida's online records, of which I take official notice, Respondent's license is "delinquent."^{*S} Florida Department of Health License Verification, <https://mqa->

^{*S} [Under the Administrative Procedure Act, an agency "may take official notice of facts at any stage in a proceeding – even in the final decision." United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). Pursuant to 5 U.S.C.

internet.doh.state.fl.us/MQASearchServices/HealthCareProviders (last visited date of signature of this Order). Respondent confirmed that her license to practice medicine in Florida had expired. Tr. 307; RE-2. Accordingly, I find that Respondent currently is not licensed to engage in the practice of medicine in Florida, the state in which Respondent has applied to transfer her DEA registration.

According to Florida statute, “A practitioner, in good faith and in the course of his or her professional practice only, may prescribe, administer, [or] dispense . . . a controlled substance.” Fla. Stat. Ann. § 893.05(1)(a). Further, “practitioner,” as defined by Florida statute, includes “a physician licensed under chapter 458.” Fla. Stat. Ann. § 893.02(23).^{*T}

Here, the undisputed evidence in the record is that Respondent’s license to practice medicine in Florida is currently delinquent. As such, she is not a “practitioner” as that term is defined by Florida statute. As already discussed, however, a physician must be a practitioner to dispense a controlled substance in Florida. Thus, because Respondent lacks authority to practice medicine in Florida, she is not currently authorized to handle controlled substances in Florida. Accordingly, I am ordering that Respondent’s application for a DEA registration in Florida be denied both because granting the application would be inconsistent with the public interest and because she lacks the requisite state authority.]

DISCUSSION AND CONCLUSIONS OF LAW

With minor modification I have sustained all of the Government’s allegations against Respondent concerning her: (1) improper storage of controlled substances; (2) failing to maintain proper inventories and dispensing logs; (3) improperly prescribing controlled

§ 556(e), “[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.” Accordingly, Registrant may dispute my finding by filing a properly supported motion for reconsideration of finding of fact within fifteen calendar days of the date of this Order. Any such motion shall be filed with the Office of the Administrator and a copy shall be served on the Government. In the event Registrant files a motion, the Government shall have fifteen calendar days to file a response. Any such motion and response may be filed and served by e-mail (dea.addo.attorneys@dea.usdoj.gov).]

^{*T} [Chapter 458 regulates medical practice.]

substances to herself and “for office use”; (4) improperly prescribing to S.P. without maintaining a medical record for S.P.; and (5) displaying a lack of candor during the investigation. In sustaining each of these allegations, I have also found that Respondent violated one or more DEA regulations, and one or more regulations of the State of California relating to the practice of medicine and/or controlled substances. I also sustained an allegation that Respondent was unable to account for a significant amount of the controlled substances that she had in her office in March of 2014 when investigators inventoried the controlled substances found in her office on June 13, 2014. Respondent’s inability to account for those controlled substances is not a separate violation of DEA regulations, but rather is a result of failure to maintain adequate records as required by both the DEA and the State of California. Finally, although the OSC alleged that Respondent had violated 21 CFR 1306.04 and the Cal. Health and Safety Code § 11350 by possessing controlled substances belonging to other individuals, I did not sustain that allegation.

Specifically, I have found that Respondent failed to properly store a significant amount of controlled substances that she kept in her office in violation of 21 CFR 1301.75(b). Her failure to do so is aggravated by the fact that after being advised on March 13, 2014, and again on April 4, 2014, that her storage was non-compliant, the controlled substances were still improperly stored on June 13, 2014. I have also found that Respondent was deficient in that she: failed to maintain an initial inventory of the controlled substances she kept at her registered location in violation of 21 U.S.C. 827(b) and 21 CFR 1304.04(a); failed to maintain complete and accurate dispensing records in violation of 21 U.S.C. 827(a)(3), 21 CFR 1304.22(c), and Cal. Health & Safety Code § 11190; and that she failed to maintain receiving records as is required by 21 U.S.C. 827 and 842(a)(5), and 21 CFR 1304.21(a). As a result of Respondent’s recordkeeping failures, the DEA was not able to conduct a reliable audit of the controlled substances Respondent stored in her office and she was not able to account for a significant amount of her controlled substances, which creates a grave risk of diversion. *See The Medicine*

Shoppe, 79 FR at 59,516. Respondent's inability to account for a significant amount of controlled substances further supports the conclusion that she violated federal law by failing to maintain complete and accurate records of those controlled substances. *Fred Samimi, M.D.*, 79 FR 18,698, 18,712-13 (2014).

In addition, I also found that Respondent had issued numerous prescriptions for no legitimate medical purpose and outside the usual course of professional practice in violation of 21 CFR 1306.04(a) and (b), and Cal. Health & Safety Code § 11170. Specifically, Respondent improperly issued 168 prescriptions between February 16, 2010 and November 29, 2012, that were either written for herself or for office use instead of for a particular patient, and between March 30, 2012 and September 16, 2014, she wrote at least 32 prescriptions for controlled substances for S.P. without having a medical record for him. Finally, I have found that Respondent was less than candid in her dealing with DEA investigators, misleading them concerning the existence and/or the location of records and her knowledge about marijuana that was found in her home.

Prima Facie Showing and Balancing

In this case Factors One and Three weigh neither for nor against revocation. However, Factors Two and Four strongly weigh in favor of revoking Respondent's COR and denying her pending application because of her improper storage, improper recordkeeping, and improper prescribing to herself and her husband. *[Omitted sentence.] Considering the public interest factors in their totality, I find that the Government has made a *prima facie* case showing that Respondent's registration is inconsistent with the public interest.

After the Government presents a *prima facie* case for revocation, a respondent has the burden of production to present "sufficient mitigating evidence" to show why she can be entrusted with a DEA registration. *See Medicine Shoppe—Jonesborough*, 73 FR 364, 387 (2008) (quoting *Samuel S. Jackson, D.D.S.*, 72 FR 23848, 23853 (2007)). To rebut the Government's *prima facie* case and escape sanction, a respondent must both accept responsibility for her

actions and demonstrate that she will not engage in future misconduct. *Patrick W. Stodola, M.D.*, 74 FR 20,727, 20,734-35 (2009). Additionally, a respondent must introduce evidence of remedial measures. *Jeri Hassman, M.D.*, 75 FR 8194, 8235-36 (2010).

A respondent may accept responsibility by providing evidence of her remorse, her efforts at rehabilitation, and her recognition of the severity of her misconduct. *See Robert A. Leslie, M.D.*, 68 FR 15,227, 15,228 (2003). To accept responsibility, a respondent must show “true remorse” for wrongful conduct. *Michael S. Moore, M.D.*, 76 FR 45,867, 45,877 (2011). An expression of remorse includes acknowledgment of wrongdoing. *See Wesley G. Harline, M.D.*, 65 FR 5665, 5671 (2000). A respondent must express remorse for all acts of documented misconduct. *Jeffrey Patrick Gunderson, M.D.*, 61 FR 26,208, 26,211 (1996). Acceptance of responsibility and remedial measures are assessed in the context of the “egregiousness of the violations and the [DEA’s] interest in deterring similar misconduct by [the] Respondent in the future as well as on the part of others.” *David A. Ruben, M.D.*, 78 FR 38,363, 38,364 (2013).

Here, the Government accurately argued in its Post-Hearing Brief that the “Respondent has not accepted responsibility for her actions.” ALJ-50, at 21. While Respondent presented limited testimony to identify Respondent’s Exhibits 1 and 2, she presented no testimony concerning the allegations contained in the OSC or concerning whether she accepted responsibility for her conduct that was proven by a preponderance of the evidence. I find, therefore, that Respondent has not accepted any responsibility for the allegations that I have sustained.³⁸

Notwithstanding the fact that the Government has made a *prima facie* case for sanction, imposing a sanction is a matter of discretion. *See* 21 U.S.C. 824(a) (“A registration . . . *may* be

³⁸ The Government has also urged that I draw an adverse inference concerning acceptance of responsibility as well as violating Federal and State laws and regulations. ALJ-50, at 22. I decline to do so. I decline simply because it is unnecessary to do so in this case. Even without the adverse inference the preponderance of the evidence establishes each of the allegations I have sustained, and the Administrative Record is already devoid of any acceptance of responsibility. *[Respondent repeatedly notes in her Exceptions that she believes an adverse inference was drawn against her for not presenting testimony at the hearing. *See* Resp Exceptions, at 3, 21, 27. It is noted that although the Government did request such an inference, the ALJ did not draw one.]

suspended or revoked by the Attorney General”) (emphasis added); *Martha Hernandez, M.D.*, 62 FR 61,145, 61,147 (1997) (referring to Administrator’s authority to exercise discretion in issuing the appropriate sanction). Even where a respondent does not accept responsibility, the DEA is still tasked with determining the appropriate sanction, and will examine: (1) “the egregiousness and extent of a registrant’s misconduct,” and (2) the DEA’s interest in specific and general deterrence. *Fred Samimi, M.D.*, 79 FR 18,698, 18,713-14 (2014); see *Daniel A. Glick, D.D.S.*, 80 FR 74,800, 74,810 (2015) (analyzing egregiousness and deterrence even though the registrant failed to tender an unequivocal acceptance of responsibility); *Jacobo Dreszer, M.D.*, 76 FR 19,386, 19,387-88 (2011) (explaining that “even though the Government has made out a *prima facie* case” for sanction, the registrant remains free to argue that “his conduct was not so egregious as to warrant revocation”).

When considering whether Respondent’s continued registration is consistent with the public interest, I must consider both the egregiousness of her violations and the DEA’s interest in deterring future misconduct by both Respondent as well as other registrants. *David A. Ruben, M.D.*, 78 FR 38,363, 38,364 (2013). “In short, this is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant’s misconduct.” *Richard J. Settles, D.O.*, 81 FR 64,940, 64,945 n.17 (2016) (quoting *Jayam Krishna-Iyer, M.D.*, 74 FR 459, 462 (2009)).

I find that Respondent’s multiple and repeated recordkeeping, security, and prescribing violations, coupled with her lack of candor, are sufficiently egregious to warrant revocation. To begin, “[r]ecordkeeping is one of the CSA’s central features; a registrant’s accurate and diligent adherence to this obligation is absolutely essential to protect against diversion of controlled substances.” *Superior Pharmacy I & Superior Pharmacy II*, 81 FR 31,310, 31,321 n.14 (2016) (quoting *Paul H. Volkman, M.D.*, 73 FR 30,630, 30,644 (2008)). Respondent’s

recordkeeping shortcomings prevented the DEA from being able to conduct a reliable audit.

Tr. 25. Due to the shortcomings, Respondent was unable to account for a significant number of controlled substances in June 2014, which creates the risk of diversion. *See The Medicine Shoppe*, 79 FR at 59,516. Respondent's storage violations also raise diversion concerns. The physical security of controlled substances is required to prevent unlawful diversion. *Jerry Neil Rand, M.D.*, 61 FR 28,895, 28,897 (1996).

In addition, while Respondent wrote 200 illegal prescriptions, only a few instances of illegal prescribing can be sufficient to support revocation of a registration. For instance, in *Alan H. Olefsky, M.D.*, the DEA imposed revocation based on evidence of only two fraudulent prescriptions.³⁹ 57 FR 928, 928-29 (1992). In *James Clopton, M.D.*, the DEA denied the respondent's application on evidence that he wrote only four unlawful prescriptions. 79 FR 2475, 2475-77 (2014). Although the record contained additional evidence of recordkeeping violations, the Administrator viewed the unlawful prescriptions as "reason alone to deny [respondent's] application." *Id.* at 2478. [*Omitted.]

Further, when determining whether revocation is appropriate, the DEA "places great weight on an [applicant's] candor, both during an investigation and in [a] subsequent proceeding." *Robert F. Hunt, D.O.*, 75 FR 49,995, 50,004 (2010). [*Omitted.] [Respondent's found lack of candor and inconsistent statements during the investigation demonstrates an unwillingness to cooperate with this agency in future compliance inspections. Truthful cooperation with agency requests for information ensures that agency officials can easily monitor and ensure compliance with the CSA and help to correct violations. *See Jeffrey Stein, M.D.*, 84 FR 46,968, 46,973 (2019) (finding that a registrant's honesty during law enforcement regulations is "crucial to the Agency's ability to complete its mission of preventing diversion within such a

³⁹ Additionally, in the *Olefsky* case, the registrant argued in his exceptions to the ALJ's recommended ruling that suspension of his license was disproportionate to the proven misconduct, which was limited to two fraudulent prescriptions presented on one occasion. 57 FR at 929. The Administrator rejected the registrant's exception and ruled that "[r]evocation [was] an acceptable remedy." *Id.*

large regulated population”). In order to entrust Respondent with a registration, I need to know that she will not repeat her dishonest behavior, and in this case, she has given me no reason to believe that I can trust her.

Furthermore, although Registrant contends that DEA and state investigators should have “point[ed] out any of the mistakes [she] made, help[ed] [her] fix her mistakes,” Resp Exceptions, at 18, the evidence on the record demonstrated that even after being explicitly told on at least two occasions that her controlled substances required additional security, she failed to adequately secure them. As such, I cannot be assured that Registrant would amend her behavior in the future to avoid repeating the violations found herein.]

Finally, as well as considering the egregiousness of Respondent’s violations, I must also consider the DEA’s interest in deterring future misconduct by both the respondent as well as other registrants. *David A. Ruben, M.D.*, 78 FR 38,363, 38,364 (2013). “Consideration of the deterrent effect of a potential sanction is supported by the CSA’s purpose of protecting the public interest.” *Joseph Gaudio, M.D.*, 74 FR at 10,094. Further, given all of the above facts, I find that considerations of both specific and general deterrence weigh in favor of revocation in this case.

RECOMMENDATION

The Government established that Respondent’s continued registration is inconsistent with the public interest because of her improper: storage; recordkeeping; and prescribing; and her lack of candor. Once the Government made a *prima facie* case for sanction, the burden shifted to Respondent to demonstrate that she could be entrusted with a DEA COR. For her part, Respondent was required to accept responsibility and demonstrate remedial measures; however, she failed to accept any responsibility for her misconduct. Respondent’s failure to acknowledge any wrongdoing whatsoever exacerbates the egregiously sub-standard manner in which she

prescribed controlled substances in this case and her total failure to properly store controlled substances after being told how to do so. A practitioner who refuses to acknowledge the severe deficiencies in her security, recordkeeping, prescribing, and candor cannot be entrusted with the ability to continue prescribing controlled substances. Accordingly, I **RECOMMEND** that Respondent's DEA COR, Number BM5370123, be **REVOKED**, and that her pending application, control number W15069021C, for renewal or modification of her registration, be **DENIED**.

Dated: April 5, 2018.

Charles Wm. Dorman ,

U.S. Administrative Law Judge.

[FR Doc. 2021-06583 Filed: 3/30/2021 8:45 am; Publication Date: 3/31/2021]